



# Implementation Guide



**OraQuick** Rapid Antibody Test  
**ADVANCE** **HIV-1/2**



OraSure Technologies

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**NOTE: In June 2004, the OraQuick ADVANCE® test was approved by the FDA for use with oral fluid specimens. While OraQuick ADVANCE® is also approved for use with fingerstick and venipuncture whole blood and plasma specimens; this guide focuses on the use of the test for the CLIA-waived matrices of fingerstick samples and non-invasive oral fluid samples.**



# Implementation Guide for Establishing a Rapid HIV Testing Program Using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test

## Executive Summary

### Purpose

This document and compendium of materials have been compiled to provide guidance and support for sites seeking to establish programs using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test to detect antibodies to the human immunodeficiency virus (HIV-1 and HIV-2) with oral fluid, plasma, fingerstick and/or venipuncture whole blood specimens.

*In June 2004, the OraQuick *ADVANCE*® test was approved by the FDA for use with oral fluid specimens. While OraQuick *ADVANCE*® is also approved for use with fingerstick and venipuncture whole blood and plasma specimens, this guide focuses on the use of the test for the CLIA-waived matrices of fingerstick samples and non-invasive oral fluid samples.*

### Background

In November 2002, OraQuick® Rapid HIV-1 Antibody Test became the first rapid HIV point-of-care test to be approved by the FDA. In January 2003, OraQuick® became the first rapid HIV test to be waived under the Clinical Laboratory Improvement Amendment (CLIA) regulations. In October 2004, OraSure Technologies launched the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, the only HIV point-of-care test for use with oral fluid specimens approved by the U.S. Food and Drug Administration (FDA). Currently OraQuick *ADVANCE*® is the only rapid HIV-1/2 Antibody test approved for use with oral fluid.

Since the launch of OraQuick® in November 2002, OraSure has been a leader in distributing millions of tests in the United States, helping people learn their HIV status in as little as 20 minutes, helping to link HIV+ patients to care.

To help ensure the quality of testing with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to the waived test kit use on either oral fluid, venipuncture and/or fingerstick whole blood specimens only<sup>†</sup> and by purchasing the test, the customer agrees to follow these restrictions.

<sup>†</sup>Plasma specimens are classified moderately complex and cannot be performed in a CLIA-waived laboratory.

The kit purchaser must:

- Be qualified to conduct this testing, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate) and any state or other certification that is required.
- Have an established quality assurance program.
- Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
- Provide information to persons being tested by giving each a copy of the manufacturer's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results.
- Not use the kit to screen blood or tissue donors.

The materials in this implementation guide are provided to assist testing sites in meeting the requirements necessary to administer the test and maintain a quality program.

### **Summary**

The three basic steps that sites needed to take to prepare for successful implementation of rapid HIV testing are:

Step 1: Enroll in CLIA

Step 2: Follow counseling guidelines

Step 3: Ensure high-quality testing and counseling

#### *Step 1 – Enroll in CLIA*

The first step in implementing a rapid HIV testing program is to enroll in CLIA. The US Congress established quality standards for all medical testing procedures when it passed the Clinical Laboratory Improvement Amendments, CLIA, in 1988. This action applies to any test that uses specimens derived from humans for the purpose of diagnosing, preventing, or treating disease. This includes all HIV tests.

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a CLIA-waived test. CLIA-waived tests are the least complicated of all medical tests that are available only to licensed professionals or testing sites. To be "CLIA-waived," a test must be simple to perform and interpret, accurate, and present no reasonable risk of harm to either the person being tested or the person performing the test. Like other medical tests, CLIA-waived tests require quality assurance measures for performing the test and counseling patients. CLIA-waived tests are not available directly to consumers.

Clinics and other facilities interested in using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test need to enroll in the CLIA program, pay a user fee, and be prepared to follow the specific test instructions described in detail in the Package Insert for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody test.

In addition to CLIA, some States have specific regulatory requirements for HIV testing. It is important to contact your State agency for information on State requirements.

Information on “How to Apply for a CLIA Certificate of Waiver” with data on State agencies is included in this guide. To obtain a Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address:

<http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>. To find your State agency contact, refer to the information provided in section 3 of this guide or at the following Internet address <http://www.cms.gov/CLIA/downloads/CLIA.SA.pdf>.

### *Step 2 – Follow Counseling Guidelines*

While obtaining CLIA certification allows you to test, the delivery of high-quality counseling will support your testing efforts and help link people to care. Any medical testing counseling must be done in a professional manner that respects the dignity of the person taking the test, as well as his or her medical and legal rights. Counselors must be fully trained to provide the best service for your clients.

HIV counseling provides information about the HIV and AIDS, the HIV test, as well as counseling clients about HIV prevention. The exact information to be provided must be individualized for each person both before and after he or she takes the HIV test. Counseling after the test will depend on whether the test result is reactive or non-reactive.

HIV counselors should be trained to provide specific information to people who will be tested with the rapid HIV antibody test. Counselors should:

- Describe the rapid test
- Tell each person that his or her test results will be available during the same visit the test is taken
- Discuss the ways HIV is transmitted and how to prevent it
- Explain the meaning of a negative rapid HIV test result using words and descriptions that the person receiving the counseling can understand
- Explain the meaning of a reactive, preliminary positive rapid HIV test result using words and descriptions that the person receiving the counseling can understand
- Explain that a reactive HIV test result requires confirmatory testing
- Tell each person where to obtain more information
- Begin the linkage to care by offering each person a list of facilities or programs that provide other HIV services, including treatment.

Regardless of whether a person's test is reactive or non-reactive, he or she should be given HIV prevention counseling. The goal is to keep each HIV-infected person from spreading the infection to other people and to help keep each person who does not have HIV from becoming infected. Prevention counseling should include the following:

- Focus on HIV risk reduction
- Include an in-depth, personalized risk assessment
- Acknowledge and provide support for positive steps already taken
- Clarify critical rather than general misconceptions about HIV risk
- Negotiate a concrete, achievable behavior-change step that will reduce HIV risk
- Seek flexibility in the counseling technique and process, avoiding a "one-size-fits-all" approach.

A Rapid Testing Counseling Protocol adopted from the counseling guidelines utilized as part of the Respect-2 Study launched by the Centers for Disease Control and Prevention (CDC) in February 1999 is included as an example in this guide.

### *Step 3 – Ensure High Quality Testing and Counseling*

The third and final step in implementing a rapid HIV testing program is to ensure that your program meets specific criteria for high-quality testing and counseling. This begins by making certain that all personnel (operators) fully understand the test procedure; they have received the appropriate training; and are deemed proficient to administer the test. You can do this in several ways.

1. Set up comprehensive training for all operators on HIV testing, counseling and linkage to care. This training should incorporate site-specific policies around quality assurance criteria, testing procedure and care recommendations.
2. Conduct quality-control tests with each operator of the rapid HIV antibody test. Quality control testing should be incorporated into initial training and then conducted minimally according to the manufacturer's recommendations but also meeting state and CLIA regulations. Kits for this quality-control test are available from OraSure Technologies.
3. Develop an ongoing quality assurance program. This will allow you to drive continuous quality improvement through monitoring and critiquing your testers and counselors in their approach with the test and test subjects. Role-playing exercises are an excellent way to evaluate and refine counseling skills.
4. For your reference, included in this implementation guide are "Quality Assurance Guidelines for Testing Using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test" – an excellent resource for establishing a quality program. This document is a revised version of the "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test" originally issued by the CDC in August, 2003.

5. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Procedure provides the specifics on administering the test and should be used to support your training efforts.

**Additional Materials**

For your reference, additional materials are included in this implementation guide to support establishing a program using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. These materials include additional sample forms (new and from existing programs) for use in establishing your quality assurance program; sample state protocols, which have been established in conjunction with select pilot programs; and additional reference materials.

**Additional Resources**

- CDC Rapid HIV Testing website (<http://www.cdc.gov/hiv/topics/testing/rapid/>)
- HIV Web Study - University of Washington- (<http://depts.washington.edu/hiv aids/cme.html>)
- [Customercare@orasure.com](mailto:Customercare@orasure.com) – for current OraQuick *ADVANCE*® customer training and support tools.





## **CDC Guidelines – Revised Recommendations on HIV Testing**

On September 22, 2006, the CDC released revised recommendations on HIV testing in the U.S. stating that HIV tests should become a routine part of medical care for residents ages 13 to 64. Additionally, the requirements for written consent and pretest counseling should be dropped for HIV screening in traditional health care settings.

Increasing the proportion of people who know their HIV status is an essential component of comprehensive HIV treatment and prevention efforts in the United States. Early diagnosis, linkage to care and initiation of HAART is critical to improve outcomes in patients with HIV. However, today, most patients who present for HIV care have a CD4 count below 350 cells/ L, the level where antiretroviral therapy initiation is generally recommended . Additionally, studies show that most people who learn they are infected take steps to protect their partners, while people who are unaware of their infection are estimated to account for between 50 percent to 70 percent of new sexually transmitted HIV infections.

While these recommendations address HIV screening in health care settings, these guidelines do not apply to non-clinical settings such as outreach programs. Additionally, CDC continues to encourage prevention counseling for all patients where feasible, especially when a health care visit is related to substance abuse, sexual health, family planning, or comprehensive health assessments.

For your reference, we've included the summary of these guidelines to review.

### **Ongoing HIV Prevention Initiatives**

Often, persons with HIV infection visit health-care settings (e.g., hospitals, acute-care clinics, and sexually transmitted disease [STD] clinics) years before receiving a diagnosis but are not tested for HIV. Since the 1980s, the demographics of the HIV/AIDS epidemic in the United States have changed. In 2008, the estimated rate of diagnoses of HIV infection in the 37 states reporting to the CDC was 19.4 per 100,000 population. In 2008, males accounted for 75% of all diagnoses of HIV infection among adults and adolescents. From 2005 through 2008, rates among American Indians/Alaska Natives, Asians, and blacks/African Americans increased with blacks/African Americans accounting for 52% of all diagnoses of HIV infection; increasing proportions of infected persons are aged <20 years, women, members of racial or ethnic minority populations, persons who reside outside metropolitan areas, and heterosexual men and women who frequently are unaware that they are at risk for HIV.\* As a result, the effectiveness of using risk-based testing to identify HIV-infected persons has diminished.

Prevention strategies that incorporate universal HIV screening have been highly effective. For example, screening blood donors for HIV has nearly eliminated transfusion-associated HIV infection in the United States. In addition, incidence of pediatric HIV/AIDS in the United States has declined substantially since the 1990s, when prevention strategies began to include specific recommendations for routine HIV testing of pregnant women. Perinatal transmission rates can be reduced to <2% with universal screening of pregnant women in combination with prophylactic administration of antiretroviral drugs, scheduled cesarean delivery when indicated, and avoidance of breast feeding.

Routine prenatal HIV testing with streamlined counseling and consent procedures has substantially increased the number of pregnant women tested. By contrast, despite repeated recommendations in support of routine risk-based testing in health care settings, the number of persons at risk for HIV infection who are screened in acute-care settings remains low. In a 2002 survey of 154 health care providers in 10 hospital emergency departments, providers reported caring for an average 13 patients per week with suspected STDs, but only 10% encouraged such patients to be tested for HIV infection in the emergency department, and 35% referred patients to confidential HIV testing sites in the community, although such referrals have proven ineffective because of poor compliance by patients. Reasons cited for not offering HIV testing in the emergency department included lack of established mechanisms to assure follow-up (51%), lack of the certification perceived as necessary to provide counseling (45%), and belief that the testing process was too-time consuming (19%). A recently published satisfaction study of an urban California Emergency Department demonstrated staff satisfaction and overall attitudes with an HIV testing program were high. And a study published in 2009 presents a practical framework to set up a rapid HIV testing program in the Emergency Department.

\*Fincher-Mergi, M., *et al.* Assessment of Emergency Department Health Care Professionals' Behaviors Regarding HIV Testing and Referral for Patients with STDs, AIDS Patient Care and STDs, Vol.16, No. 11, 2002.

With routine HIV screening in some hospitals and emergency departments, the percentage of patients with positive tests (2% to 7%) often exceeds that observed nationally in publicly funded HIV counseling and testing sites (1.5%) and STD clinics (2.0%) serving high-risk persons. Because patients were rarely seeking testing when screening was offered, many HIV infections were identified earlier than might otherwise have been the case. Targeted testing programs have also been implemented in acute-care settings; nearly 2/3 of patients accept screening, but because risk assessment and prevention counseling are resource intensive, only a small minority of eligible patients can be tested. Targeted testing on the basis of behavioral risks also fails to identify many HIV-infected persons. Many persons, including many with HIV infection, do not perceive their HIV risks or do not disclose them. Further, performing testing routinely reduces the stigma associated with testing that requires ascertainment of behavioral risks. More patients accept recommended HIV testing when it is offered routinely to everyone, without a risk assessment.

In December 2009, the Centers for Medicare and Medicaid Services (CMS) determined that screening for HIV infection, which is recommended with a grade of A by the U.S. Preventive Services Task Force (USPSTF) for certain individuals (including persons who request an HIV test despite reporting no individual risk factors), is reasonable and necessary for early detection of HIV and is appropriate. The U.S. Preventive Services Task Force has concluded that there is good evidence that appropriately timed interventions, particularly highly active antiretroviral therapy, lead to improved health outcomes with earlier HIV diagnosis, including slower clinical progression and reduced mortality. HIV-positive persons reduce high-risk behavior substantially when they become aware of their infection. Because viral load is the chief predictor of HIV transmission, reduction in viral load through timely initiation of highly active antiretroviral therapy may reduce transmission, even if HIV-positive patients did not change their risk behavior.

## **CDC Guideline Recommendations for Adults and Adolescents\***

### **Screening for HIV infection:**

- In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13-64 years. Health-care providers should initiate screening unless the prevalence of undiagnosed HIV infection in the patients has been documented to be <0.1%. In the absence of existing data for the HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is less than 1 per 1000 patients screened, at which point such screening is no longer warranted.
- All patients initiating treatment for tuberculosis should be routinely screened for HIV infection.
- All patients seeking treatment for STDs, including patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavioral risks for HIV infection.

### **Repeat screening:**

- Health-care providers should subsequently test all persons likely to be at high risk for HIV at least annually. Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.
- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.
- Repeat screening of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment.
- Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health-care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs.

\*Excerpts from the CDC's Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health-Care Settings, 9/22/06.

**Consent and pre-test information:**

- Screening should be voluntary and undertaken only with the patient's knowledge and understanding that testing is planned.
- Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt-out screening). Oral or written information should include an explanation of HIV infection and the meanings of positive and negative test results, and the patient should be offered an opportunity to ask questions and to decline testing. With such notification, consent for HIV screening should be incorporated into the patient's general informed consent for medical care on the same basis as are other screening or diagnostic tests; a separate consent form for HIV testing is not recommended.
- Easily understood informational materials should be made available in the languages of the commonly encountered populations within the service area. The competence of interpreters and bilingual staff to provide language assistance to patients with limited English proficiency must be ensured.
- If a patient declines an HIV test, this decision should be documented in the medical record.

**Diagnostic testing for HIV infection:**

- All patients with signs and symptoms consistent with HIV infection or an opportunistic disease characteristics of AIDS should be tested for HIV.
- Clinicians should maintain a high level of suspicion for acute HIV infection in all patients presenting with a compatible clinical syndrome and who report recent high-risk behavior. When acute retroviral syndrome is suspected, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection.
- Patients or persons responsible for patient's care should be notified orally that testing is planned, advised of the indication for testing and the implications of positive and negative test results, and offered an opportunity to ask questions and to decline testing. With such notification, the patient's general consent for medical care may be considered sufficient for diagnostic HIV testing.

## **Recommendations for Pregnant Women\***

### **Universal Opt-Out Screening:**

- All pregnant women in the United States should be screened for HIV infection.
- Screening should occur after a woman is notified that HIV screening is recommended for all pregnant patients and that she will receive an HIV test as part of the routine panel of prenatal tests unless she declines (opt-out screening).
- HIV testing must be voluntary and free from coercion. No woman should be tested without her knowledge.
- Pregnant women should receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative test results and should be offered an opportunity to ask questions and to decline testing.
- No additional process or written documentation of informed consent beyond what is required for other routine prenatal tests should be required for HIV testing.
- If a patient declines an HIV test, this decision should be documented in the medical record.

### **Addressing Reasons for Declining Testing:**

- Providers should discuss and address reasons for declining an HIV test (e.g. lack of perceived risk; fear of the disease; and concerns regarding partner violence or potential stigma or discrimination).
- Women who decline an HIV test because they have had a previous negative test result should be informed of the importance of retesting during each pregnancy.
- Logistical reasons for not testing (e.g., scheduling) should be resolved.
- Certain women who initially decline an HIV test might accept at a later date, especially if their concerns are discussed. Certain women will continue to decline testing, and their decisions should be respected and documented in the medical record.

### Timing of HIV Testing:

- To promote informed and timely therapeutic decisions, health-care providers should test women for HIV as early as possible during each pregnancy. Women who decline the test early in prenatal care should be encouraged to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferably <36 weeks of gestation, is cost-effective even in areas of low HIV prevalence and may be considered for all pregnant women. A second HIV test during the third trimester is recommended for women who meet one or more of the following criteria:

–Women who receive health care in jurisdictions with elevated incidence of HIV and AIDS among women aged 15-45 years. In 2004, these jurisdictions included Alabama, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, Mississippi, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, and Virginia.<sup>†</sup>

<sup>†</sup>A second HIV test in the third trimester is as cost-effective as other common health interventions when HIV incidence among women of childbearing age is 17 HIV cases per 100,000 person-years. In 2004, in jurisdictions with available data on HIV case rates, a rate of 17 new HIV diagnoses per year per 100,000 women aged 15-45 years was associated with an AIDS case rate of at least nine AIDS diagnoses per year per 100,000 women aged 15-45 years (CDC, unpublished data, 2005). As of 2004, the jurisdictions listed above exceeded these thresholds. The list of specific jurisdictions where a second test in the third trimester is recommended will be updated periodically based on surveillance data.

–Women who receive health care in facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened.

–Women who are known to be at high risk for acquiring HIV (e.g., injection-drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy).

–Women who have signs or symptoms consistent with acute HIV infection. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection.



**Rapid testing during labor:**

- Any woman with undocumented HIV status at the time of labor should be screened with a rapid HIV test unless she declines (opt-out screening).
- Reasons for declining a rapid test should be explored (see Addressing Reasons for Declining Testing).
- Immediate initiation of appropriate antiretroviral prophylaxis should be recommended to women on the basis of a reactive rapid test result without waiting for the result of a confirmatory test.

**Postpartum/newborn testing:**

- When a woman's HIV status is still unknown at the time of delivery, she should be screened immediately postpartum with a rapid HIV test unless she declines (opt-out screening).
- When the mother's HIV status is unknown postpartum, rapid testing of the newborn as soon as possible after birth is recommended so antiretroviral prophylaxis can be offered to HIV-exposed infants. Women should be informed that identifying HIV antibodies in the newborn indicates that the mother is infected.
- For infants whose HIV exposure status is unknown and who are in foster care, the person legally authorized to provide consent should be informed that rapid HIV testing is recommended for infants whose biologic mothers have not been tested.
- The benefits of neonatal antiretroviral prophylaxis are best realized when it is initiated 12 hours after birth.

**Confirmatory testing:**

- Whenever possible, uncertainties regarding laboratory test results indicating HIV infection status should be resolved before final decisions are made regarding reproductive options, antiretroviral therapy, cesarean delivery, or other interventions.
- If the confirmatory test results is not available before delivery, immediate initiation of appropriate antiretroviral prophylaxis should be recommended to any pregnant patient whose HIV screening test result is reactive to reduce the risk for perinatal transmission.

In an ongoing effort to reduce mother-to-infant transmission of HIV infection, the CDC offers the *One Test. Two Lives.* campaign, which offers information to help pregnant patients be tested. More information can be obtained at [www.cdc.gov/hiv/topics/perinatal/1test2lives/default.htm](http://www.cdc.gov/hiv/topics/perinatal/1test2lives/default.htm).

*How to apply for a*



# CLIA Certificate of Waiver

## Clinical Laboratory Improvement Amendments (CLIA) Background

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The Centers for Medicare and Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The FDA is responsible for test categorization.

# Completing the application form

## Section 1 - General Information

- > The CLIA application form (CMS-116) can be obtained at the CMS website:  
[www.cms.gov/cmsforms/downloads/cms116.pdf](http://www.cms.gov/cmsforms/downloads/cms116.pdf).

You must have Adobe Acrobat Reader installed on your computer in order to view and print this document. A link on the CMS site has been provided for obtaining the free viewing software if it is not already installed on your computer system.

### Name of Director

- > This person should be identified as the principle party responsible for overseeing testing programs, ensuring that facility personnel administering testing are fully trained, and documentation is maintained to meet CLIA standards. States deemed as "State Licensure" or "Exempt" may require additional accreditation within their individual states to qualify (e.g. medical director with licensed medical degree, etc.). *Refer to state listing for the states that may apply.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES			Form Approved OMB No. 0938-0581		
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION					
<b>I. GENERAL INFORMATION</b>			CLIA IDENTIFICATION NUMBER		
<input checked="" type="checkbox"/> Initial Application <input type="checkbox"/> Survey			Leave Blank for New Applications		
<input type="checkbox"/> Change in Certification Type			D		
<input type="checkbox"/> Other Changes (Specify)			(If an initial application leave blank, a number will be assigned)		
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER		
The Family Center of PA			12-3456789		
EMAIL ADDRESS			TELEPHONE NO. (Include area code)	FAX NO. (Include area code)	
			(610)345-6789	(610)345-6788	
FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this address unless mailing address is specified			MAILING/BILLING ADDRESS (If different from street address)		
The Family Center of PA			The Family Center of PA		
Attn: Accounts Payable					
NUMBER, STREET (No P.O. Boxes)			NUMBER, STREET		
123 East First Street - Suite 100			123 East First Street - Suite 100		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
Reading	PA	12345	Reading	PA	12346
NAME OF DIRECTOR (Last, First, Middle Initial)			FOR OFFICE USE ONLY		
Taylor, John, S.			Date Received		
<b>II. TYPE OF CERTIFICATE REQUESTED (Check only one)</b>					
<input checked="" type="checkbox"/> Certificate of Waiver (Complete Sections I – VI and IX – X)					
<input type="checkbox"/> Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)					
<input type="checkbox"/> Certificate of Compliance (Complete Sections I – X)					
<input type="checkbox"/> Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes					
<input type="checkbox"/> The Joint Commission <input type="checkbox"/> AOA <input type="checkbox"/> AABB					
<input type="checkbox"/> CAP <input type="checkbox"/> COLA <input type="checkbox"/> ASHI					
If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.					
<b>NOTE:</b> Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.					

## Section 2 - Type of Certificate

### Certificate of

- > Check box indicated.

<b>II. TYPE OF CERTIFICATE REQUESTED (Check only one)</b>	
<input checked="" type="checkbox"/> Certificate of Waiver (Complete Sections I – VI and IX – X)	
<input type="checkbox"/> Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)	
<input type="checkbox"/> Certificate of Compliance (Complete Sections I – X)	
<input type="checkbox"/> Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes	
<input type="checkbox"/> The Joint Commission <input type="checkbox"/> AOA <input type="checkbox"/> AABB	
<input type="checkbox"/> CAP <input type="checkbox"/> COLA <input type="checkbox"/> ASHI	
If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.	
<b>NOTE:</b> Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.	

### Section 3 - Type of Laboratory

#### Facility Identification

- > This should be checked off from the description that best describes the type of facility and services provided.

**III. TYPE OF LABORATORY** (Check the one most descriptive of facility type)

<input type="checkbox"/> 01 Ambulance	<input type="checkbox"/> 11 Health Main. Organization	<input type="checkbox"/> 22 Practitioner Other (Specify)
<input type="checkbox"/> 02 Ambulatory Surgery Center	<input type="checkbox"/> 12 Home Health Agency	
<input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility	<input type="checkbox"/> 13 Hospice	<input type="checkbox"/> 23 Prison
<input type="checkbox"/> 04 Assisted Living Facility	<input type="checkbox"/> 14 Hospital	<input type="checkbox"/> 24 Public Health Laboratories
<input type="checkbox"/> 05 Blood Bank	<input type="checkbox"/> 15 Independent	<input type="checkbox"/> 25 Rural Health Clinic
<input checked="" type="checkbox"/> 06 Community Clinic	<input type="checkbox"/> 16 Industrial	<input type="checkbox"/> 26 School/Student Health Service
<input type="checkbox"/> 07 Comp. Outpatient Rehab Facility	<input type="checkbox"/> 17 Insurance	<input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility
<input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility	<input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded	<input type="checkbox"/> 28 Tissue Bank/Repositories
<input type="checkbox"/> 09 Federally Qualified Health Center	<input type="checkbox"/> 19 Mobile Laboratory	<input type="checkbox"/> 29 Other (Specify)
<input type="checkbox"/> 10 Health Fair	<input type="checkbox"/> 20 Pharmacy	
	<input type="checkbox"/> 21 Physician Office	

Is this a shared lab? ☐ Yes ☐ No

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format)

### Section 4 - Hours of Laboratory Testing

#### Hours of Operation

- > Indicate when testing services will be available at the test site. This may or may not mirror site location's operating hours.

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:		9:00	9:00	9:00	9:00	9:00	8:00
TO:		5:00	5:00	5:00	5:00	5:00	3:30

(For multiple sites, attach the additional information using the same format.)

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?  
☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?  
☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
☐ Yes ☐ No  
If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
☐ Yes ☐ No  
If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

### Section 5 - Multiple Sites

#### Multiple Locations

- > Most applications will respond "NO" to this question. Check off as indicated if applicable and immediately go to Section 6.

For applications that have multiple location sites, contact your local CMS office to ensure that the regulatory exceptions for this provision are met prior to completing this form. Additionally, Section 5 will require that each location's testing hours are identified.

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?  
☒ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?  
☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
☐ Yes ☐ No  
If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
☐ Yes ☐ No  
If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)

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## Section 6 - Waived Testing

### Annual Test Volume

- > This number represents the total estimate number of tests that will be performed at the testing facility annually. Under CLIA Application of Waiver submission, the fee charged for a two-year certificate is \$150.00, regardless of the volume of CLIA waived tests conducted within a facility. Whereas, CLIA Certificates for Moderate Complexity and High Complexity are fee rendered by this number indicated as well as the type of testing performed as identified under Section 7.

In the next three sections, indicate testing performed and annual test volume.

**VI. WAIVED TESTING**  
Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.  
e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed 1,500

☐ Check if no waived tests are performed

**VII. PPM TESTING**  
Identify the tests performed.

## Skip Section 7 & 8 IF YOU ARE ONLY CONDUCTING WAIVED TESTING

## Section 9 - Type of Control

### Facility Overseer

- > Indicate which code closely identifies with your organization. This would be understood by how you are identified currently with the IRS for tax filing purposes.

**IX. TYPE OF CONTROL**

<b>VOLUNTARY NONPROFIT</b> <input type="checkbox"/> 01 Religious Affiliation <input checked="" type="checkbox"/> 02 Private Nonprofit <input type="checkbox"/> 03 Other Nonprofit (Specify) _____	<b>FOR PROFIT</b> <input type="checkbox"/> 04 Proprietary	<b>GOVERNMENT</b> <input type="checkbox"/> 05 City <input type="checkbox"/> 06 County <input type="checkbox"/> 07 State <input type="checkbox"/> 08 Federal <input type="checkbox"/> 09 Other Government (Specify) _____
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**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

## Section 10 - Director Affiliation with Other Laboratories

### Other Affiliations

- > Many identified Directors may have affiliations with other facilities and/or programs within each state. This section must be completed if the Director identified for this application has been registered to other site locations and/or organizations.

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
41D1234567	Eastern Pennsylvania Crisis Center

ATTENTION: BE CAREFUL TO

## Section 10 - Director Affiliation with Other Laboratories

### Contractual Obligation

- > The Laboratory Director must sign and complete the application. By signing this application, the Director agrees to permit the Secretary, or any Federal officer or employee designated by the Secretary to inspect the laboratory, operations and all records at any reasonable time to determine applicants eligibility or continued eligibility for a CLIA certificate and continued compliance with CLIA requirements are met.

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION	
<p>Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.</p> <p>Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.</p>	
SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign in ink) <b>John S. Taylor</b>	DATE <b>03/02/2011</b>
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## Mail

### Completed Application

- > Once the application is completed, it should be mailed directly to the local CMS office in your state. No check or money order should be sent at this time. The application is then entered into a national database. Within the next two (2) weeks, a bill with a detachable coupon will be mailed to the attention of the Director. Fees for a Certificate of Waiver for two years will be \$150.00. Detach the coupon and send along with payment to the address provided. Be sure to reference the assigned CLIA certificate number on your check should the coupon be lost or separated from payment.

# CLIA Certificate of Waiver

- > Processing for a new certificate may take up to two months, however calling your local office may or may not yield information on the progress of your application. Your CLIA certificate number is established on your original invoice. Only once your payment is credited may you begin testing within your facility. The CLIA certificate will arrive approximately two (2) weeks following credited payment.

## Renewal

- > Anticipate ten months prior to renewal date of your CLIA Certificate, a coupon voucher to arrive directed to the listed Director of the facility. Payment should be made by expected due date. Any changes from the original application should also be indicated. Once payment is received a renewal Certificate will be sent one month prior to the expiration date.

**For additional information, contact your local CMS office.**

## State Survey Agencies (CLIA Contact List)

	CLIA	State Licensure	Exempt		CLIA	State Licensure	Exempt		CLIA	State Licensure	Exempt
<b>REGION I - Boston</b>											
CLIA LABORATORY PROGRAM DEPARTMENT OF PUBLIC HEALTH P. O. Box 340308 410 Capitol Avenue, MS#12 HSR Hartford, CT 06134-0308 (860) 509-7400 FAX: (860) 509-7543 Contact: John J. Murphy	●			<b>For Physician Office Laboratories in New York:</b> STATE OF NEW YORK DEPARTMENT OF HEALTH PHYSICIAN OFFICE LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5352 Contacts: Dr. Michael P. Ryan	●			VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LICENSURE AND CERTIFICATION 9600 Mayland Drive, Suite 401 Richmond, VA 23233 (804) 367-2107 FAX: (804) 527-4504 Contact: Sarah Pendergrass	●		
BUREAU OF HEALTH CARE SAFETY AND QUALITY MASS. DEPT. OF PUBLIC HEALTH CLINICAL LABORATORY PROGRAM 99 Chauncy Street, 11th Floor Boston, MA 02111 (617) 753-8438 or 8439 FAX: (617) 753-8240 Contact: Roberta Teixeira	●			<b>For All Other Laboratory Facility Types in New York:</b> CLINICAL LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5378 Contacts: Stephanie Shulman	●			WEST VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LABORATORY SERVICES 167 11th Avenue South Charleston, WV 25303-1137 (304) 558-3530, extension 2103 FAX: (304) 558-2006 Contact: Jerry Gross		●	
DIVISION OF FACILITIES REGULATION RI DEPARTMENT OF HEALTH 3 Capitol Hill, Room 306 Providence, RI 02908 (401) 222-4526 FAX: (401) 222-3999 Contact: Nancy Hines	●			COMMONWEALTH OF PUERTO RICO PUERTO RICO HEALTH DEPARTMENT OFFICE OF CERTIFICATION & LICENSURE FORMER-RUIZ SOLER HOSPITAL Road No. 2 Bayamon PR 00619 (787) 782-0120 Ext. 2222 FAX: (787) 781-2088 Contact: Julia Colón	●			<b>REGION IV - Atlanta</b>			
CLIA PROGRAM DIVISION OF LICENSING & REGULATORY SERVICES 41 Anthony Avenue, Station #11 Augusta, ME 04333-0011 (207) 287-9339 FAX: (207) 287-9304 Contact: Dale Payne	●			<b>REGION III - Philadelphia</b>				ALABAMA DEPARTMENT OF PUBLIC HEALTH DIVISION OF HEALTH CARE FACILITIES CLIA PROGRAM, P.O. Box 303017 Montgomery, AL 36130-3017 (334) 206-5120 Contact: Faye Allen	●		
HEALTH FACILITIES ADMINISTRATION DEPARTMENT OF HEALTH & HUMAN SERVICES 129 Pleasant Street Concord, NH 03301 (603) 271-4832 FAX: (603) 271-4968 Contact: Rodney Bascom	●			DELAWARE STATE PUBLIC HEALTH LABORATORY 30 Sunnyside Road Smyrna, DE 19977 (302) 223-1392 FAX: (302) 653-2877 Contact: Donna Phillips-DiMaria	●			STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION LABORATORY LICENSING UNIT 2727 Mahan Drive, Mail Stop 32 Tallahassee, FL 32308 (850) 412-4500 FAX: (850) 410-1511 Contact: Karen Rivera		●	
CLIA LABORATORY PROGRAM VERMONT DEPARTMENT OF HEALTH 108 Cherry Street Burlington, VT 05401 (802) 652-4145 FAX: (802) 865-7701 Contact: Carol Drawbaugh	●			DC DEPARTMENT OF HEALTH Health Regulations and Licensing Administration Health Facilities Division - Laboratory Services 899 North Capitol Street, NE-2nd Floor Washington, DC 20002 (202) 727-1740 FAX: (202) 442-9431 Contact: Semret Tesfaye	●			DEPARTMENT OF COMMUNITY HEALTH HEALTHCARE FACILITY REGULATION DIVISION DIAGNOSTIC SERVICES UNIT 2 Peachtree Street, N.W., Suite 31-447 Atlanta, GA 30303-3142 (404) 657-5447 FAX: (404) 657-5442 Contact: Sheela E. Puthumana		●	
<b>REGION II - New York</b>				MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENNE OFFICE OF HEALTH CARE - LABS Bland Bryant Building Spring Grove Hospital Center 55 Wade Avenue Catonsville, MD 21228 (410) 402-8025 FAX: (410) 402-8213	●			KENTUCKY CLIA PROGRAM Office of Inspector General 275 E Main Street 5E-A Frankfort, KY 40601 (502) 564-7963 Contact: Connie Barker, Ext. 3280	●		
CLINICAL LABORATORY IMPROVEMENT SVC STATE OF NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES P. O. Box 361 Trenton, NJ 08625-0361 (609) 292-0016 FAX: (609) 292-0424 Contact: Marilou Mallada	●			PENNSYLVANIA DEPARTMENT OF HEALTH BUREAU OF LABORATORIES 110 Pickering Way Exton, PA 19341-0500 (610) 280-3464 Ext. 3233 FAX: (610) 594-9763 Contact: Melissa Sealle	●			LICENSURE AND CERTIFICATION MISSISSIPPI DEPARTMENT OF PUBLIC HEALTH P. O. Box 1700 Jackson, MS 39215-1700 (601) 364-1115 Contact: Theresa Irwin	●		

CLIA	State Licensure	Exempt	CLIA	State Licensure	Exempt	CLIA	State Licensure	Exempt
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF FACILITY SERVICES/ CLIA CERTIFICATION 2713 Mail Service Center Raleigh, NC 27699-2713 (919) 855-4620 FAX: (919) 733-0176 Contact: Azzie Conley	●		OKLAHOMA STATE DEPARTMENT OF HEALTH PROTECTIVE HEALTH SERVICES MEDICAL FACILITIES 1000 NE 10th Street Oklahoma City, OK 73117-1299 (405) 271-6576 Contact: Dean Bay	●		REGION IX - San Francisco		
SOUTH CAROLINA DEPARTMENT OF HEALTH & ENVIRONMENTAL CONTROL BUREAU OF CERTIFICATION/ HEALTH REGULATION 2600 Bull Street Columbia, SC 29201 (803) 545-4291 FAX: (803) 545-4563 Contact: Lakeisha N. Wright	●		TEXAS DEPARTMENT OF STATE HEALTH SERVICES ATTN: Charles Peck P. O. Box 149347 Austin, TX 78714-9347 (512) 834-6792	●		ARIZONA DEPARTMENT OF HEALTH SERVICES DIVISION OF PUBLIC HEALTH SERVICES Office of Laboratory Services 250 N. 17th Avenue Phoenix, AZ 85007 (602) 364-0741 FAX: (602) 364-0759 Contact: Odalys Hinds	●	
TENNESSEE HEALTH CARE FACILITIES 227 French Landing, Suite 501 Heritage Place Metro Center Nashville, TN 37243 (615) 741-7023 FAX: (615) 532-2700 Contact: Sandra Bogard	●		REGION VII - Kansas City			DEPARTMENT OF PUBLIC HEALTH DIVISION OF LABORATORY SERVICES LABORATORY FIELD SERVICES 320 West 4th Street, Suite 890 Los Angeles, CA 90013-2398 (213) 620-6160 FAX: (213) 620-6565 Contact: Donna McCallum, Examiner III	●	
ILLINOIS DEPARTMENT OF PUBLIC HEALTH DIVISION OF HEALTH CARE FACILITIES & PROGRAMS 525 W Jefferson Street Fourth Floor Springfield, IL 62761 (217) 782-2343 FAX: (217) 782-0382 Contact: Juan Garcis, Supervisor	●		IOWA CLIA LABORATORY PROGRAM STATE HYGIENIC LABORATORY Research Park The University of Iowa Iowa City, IA 52242 (319) 335-4500 FAX: (319) 335 4174 Contact: Nancy Grove, Sr. Laboratory Consultant	●		HAWAII DEPARTMENT OF HEALTH CLIA Program 601 Kamokila Blvd., Room 395 Kapolei, HI 96707 (808) 692-7420 FAX: (808) 692-7447 Contact: Susan O. Naka	●	
INDIANA STATE DEPARTMENT OF HEALTH DIVISION OF ACUTE CARE SERVICES 2 North Meridian Street, Room 4A Indianapolis, IN 46204 (317) 233-7502 FAX: (317) 233-7157 Contact: Lorraine Switzer	●		KANSAS DEPARTMENT OF HEALTH & ENVIRONMENT LABORATORY CERTIFICATION Building 740 Forbes Field Topeka, KS 66620-0001 (785) 296-3811 Contact: Ruby Brower	●		FOR LABS IN AMERICAN SAMOA (64), CONTACT THE HAWAII STATE AGENCY (12) FOR LABS IN SAIPAN (66) AND GUAM (65), CONTACT REGIONAL OFFICE IX, SAN FRANCISCO		
MICHIGAN DEPARTMENT OF COMMUNITY LABORATORY IMPROVEMENT SECTION 611 W. Ottawa Street, First Floor Lansing, MI 48909 (517) 241-2648 FAX: (517) 241-3354	●		MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES CLIA Section P. O. Box 570 Jefferson City, MO 65102 (573) 751-6318 Contact: William Nugent	●		STATE OF NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH DIVISION BUREAU OF HEALTH CARE QUALITY & COMPLIANCE 727 Fairview Dr., Ste E Carson City, NV 89701-5493 (775) 684-1060 FAX: (775) 684-1073 Contact: Vicki Estes, MT (ASCP)	●	
MINNESOTA DEPARTMENT OF HEALTH LICENSING & CERTIFICATION CLIA PROGRAM 85 East 7th Place P. O. Box 64900 St. Paul, MN 55164-0900 (651) 215-8420 FAX: (651) 215-9697 Contacts: Bridget Woitas	●		NEBRASKA STATE HEALTH & HUMAN SERVICES LICENSURE UNIT-DIVISION OF PUBLIC HEALTH Office of Acute Care Facilities P. O. Box 94986 Lincoln, NE 68509-4986 (402) 471-3484 Contact: Joann Erickson	●		REGION X - Seattle		
OHIO DEPARTMENT OF HEALTH LABORATORY CLIA LABORATORY PROGRAM 246 N. High Street, 3rd Floor Columbus, OH 43215 (614) 644-1845 FAX: (614) 387-2762 Contact: Drema Phelps	●		REGION VIII - Denver			OFF. OF LABORATORY QUALITY ASSURANCE DEPARTMENT OF HEALTH 1610 NE 150TH Street Shoreline, WA 98155-9701 (206) 418-5418 FAX: (206) 418-5505 Contact: Susan Walker	●	
DEPARTMENT OF HEALTH SERVICES DIVISION OF QUALITY ASSURANCE CLINICAL LABORATORY SECTION 1 W. Wilson Street, Room 1151 Madison, WI 53701-2969 (608) 261-0653 FAX: (608) 264-9847 Contact: Barbara Saar	●		COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT LABORATORY SERVICES DIVISION 8100 Lowry Blvd. Denver, CO 80230-6928 (303) 692-3681 FAX: (303) 344-9965 Contact: Jeff Groff	●		OREGON HEALTH AUTHORITY OREGON STATE PUBLIC HEALTH DIVISION LABORATORY COMPLIANCE SECTION (LCS) 3150 NW 229th Avenue, Suite 100 Hillsboro, OR 97124-6536 (503) 693-4121 FAX: (503) 693-5602 Contact: Rita A. Youell	●	
HEALTH FACILITY SERVICES Slot H9 ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES 5800 West 10th Street, Suite 400 Little Rock, AR 72204-9916 (501) 661-2201 Contact: Liz Davis	●		MONTANA CLIA PROGRAM - DIVISION OF QUALITY ASSURANCE - DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES 2401 Colonial Drive, 2nd Floor P. O. Box 202953 Helena, MT 59620-2953 (406) 444-1451 FAX: (406) 444-3456 Contact: Ed Adams	●		LABORATORY IMPROVEMENT SECTION BUREAU OF LABORATORIES 2220 Old Penitentiary Road Boise, ID 83712-8299 (208) 334-2235 x245 FAX: (208) 334-4067 Contact: David Eisentrager	●	
DEPARTMENT OF HEALTH & HOSPITALS HEALTH STANDARDS SECTION 500 Laurel Street, Suite 100 Baton Rouge, LA 70801 (225) 342-9324 Contact: Staci Glueck	●		HEALTH RESOURCES SECTION NORTH DAKOTA DEPARTMENT OF HEALTH STATE CAPITAL 600 East Boulevard Avenue/DEPT 301 Bismarck, ND 58505-0200 (701) 328-2352 FAX: (701) 328-1890 Contact: Bridget Weidner	●		ALASKA CLIA PROGRAM ALASKA STATE PUBLIC HEALTH LABORATORY 5455 Dr. Martin Luther King Jr. Avenue Anchorage, AK 99507 (907) 334-2583 FAX: (907) 334-2161 Contact: Doris Thompson	●	
HEALTH FACILITY LICENSING AND CERTIFICATION BUREAU Bank of the West Building 5301 Central Avenue NW, Suite 400 Albuquerque, NM 87108 (505) 222-8646 Fax: (505) 841-5834 Contact: Julie Aragon	●		SOUTH DAKOTA DEPARTMENT OF HEALTH OFFICE OF HEALTH CARE FACILITIES LICENSURE AND CERTIFICATION 615 E. 4th Street Pierre, SD 57501-1700 (605) 773-3694 FAX: (605) 773-6667 Contact: Connie Richards	●				
			UNIFIED STATE LABORATORIES:PUBLIC HEALTH BUREAU OF LABORATORY IMPROVEMENT 4431 South 2700 West Taylorsville, UT 84119 (801) 965-2531 FAX: (801) 965-2544 Contact: Jan Case	●				
			OFFICE OF HEALTHCARE LICENSING AND SURVEYS 400 Qwest Building 6101 North Yellowstone Road Cheyenne, WY 82002 (307) 777-7123 FAX: (307) 777-7127 Contact: Russ Forney	●				



# CLIA Important Information

## State Licensure or Exemption

- > Prior to the introduction of the Clinical Laboratory Improvement Amendments of 1988, numerous states had already adopted quality procedures and protocols by which laboratories operating within the state had to maintain. Many of these already established guidelines were deemed more stringent than the new protocols established under 42 CFR Part 493. Petitions were heard and granted that allow for states with already existing protocols that proved to be “equal to or more stringent” may apply for a CLIA “Exemption”. To date, New York and Washington are the only two states operating under exemption whereas there are 17 states that have “State Licensure” in addition to CLIA. The previous chart assists in identifying these. Under State Licensure however, additional guidelines may be required in order to perform CLIA waived testing within the given state. These may include Proficiency Testing, Training Requirements, Quality Assurance Programs and Testing Procedures, Record Keeping Requirements, etc. For any application within these states, contact your local office to determine what additional steps and filings may be required to perform CLIA waived testing.

## Additions or Changes to Issued Certificates

- > During the two-year certificate period, information supplied on the original certificate application may change (e.g., lab director, add-on site location, etc). It is important that this information be communicated in a prompt manner to the local State Reporting office. The local states maintain the database for each issued certificate within the state. For questions concerning changes to the current certificate status, it is best to contact your local CMS office for clarification. Most often a simple letter is all that is required. This will be kept on file at the state office. A new certificate **will not** be issued reflecting these changes. Only upon renewal application will the changed information be indicated.

## Facility Inspections

- > The local state offices of CMS inspect facilities from time to time to monitor and ensure that each is operating under the CLIA guidelines. While these inspections are not punitive in nature, inspectors will check to see that Manufacturers’ Guidelines are followed within each facility. Additionally, reported complaints in the field will prompt a mandatory inspection of any facility. A report will be written for both random and mandated inspections that will advise any inconsistencies and recommendations to bring a facility up to compliance. Timelines for compliance adherence will be established. What can this mean potentially to a CLIA waived testing site? If a second follow-up inspection reveals that conformance has not been established, the local CMS office can cease CLIA testing operations for a given time to that facility or site until conformance has been satisfactorily met. Similarly, if additional complaints are filed against the facility, CLIA certification can be permanently revoked and punitive action can take place dependent on the nature of the complaint.

# Rapid Testing Counseling Protocol

The following Rapid Testing Counseling Protocol has been adopted from the counseling protocol utilized as part of the Respect – 2 Study launched by the Centers for Disease Control and Prevention in February 1999. More information on the Respect – 2 counseling protocols can be found at:

<http://www.cdc.gov/hiv/projects/respect-2/counseling.htm>

- I. Pre-Test Counseling (*Total Time: 10-18 minutes*)**
  - A. Introductions and Orientation to the Session (2-4)
  - B. Enhancement of Patient's Self-Perception of Risk (2-3)
  - C. Explore the Specifics of Most Recent Risk Incident (2-3)
  - D. Review Previous Risk Reduction Experiences (2-4)
  - E. Synthesis of Risk Incident and Risk Pattern (2-4)
- II. Post-Test Counseling (*Total Time: 10-21 minutes*)**
  - F. Provide Test Results (2-10)
  - G. Negotiate Risk Reduction Plan (4-5)
  - H. Identify Sources of Support and Provide Additional Referrals (3-4)
  - I. Provide Appointment Card/Reminder for Follow-up (1-2)

## **I. Pre-Test Counseling**

### **A. Introductions and Orientation to the Session (2-4)**

To establish initial rapport with the patient, the counselor will need to convey positive regard, genuine concern and an empathic response toward the patient. This connection will help build trust and will set the tone for the rest of the session. The counselor must be professional and respectful toward the patient and recognize that issues of sex and drug use behaviors may be sensitive and difficult for the patient to discuss.

The patient should be helped to feel comfortable with the clinic procedures, understand the role of the counselor, and be clear about the content and purpose of the session. If the patient is clear about the expectations and the process, the counselor has reduced the patient's anxiety and increased the patient's ability to focus on the session. This clear delineation of the session serves to model for the patient a rational and responsible approach to addressing the challenging issues of behavior change. It is important that the counselor conduct the session, to the extent possible, as described to the patient. If the counselor must deviate from what he/she has indicated will occur in the session, this change should be explained to the patient.

The counselor should convey confidence in being able to understand the patient's risk behavior and in the patient's ability to initiate a risk reduction process. Also, the counselor should communicate an appropriate sense of urgency and concern relative to the patient's HIV/STD risks. In this component of the session, the counselor should establish the collaborative nature of the session and the mutual commitment of both counselor and patient to earnestly address risk reduction issues.

## **B. Enhancement of Patient's Self-Perception of Risk (2-3)**

The counselor is attempting to focus the patient's attention on his/her behavior and the corresponding risk of acquiring HIV/STD. The counselor's approach to this component of the session will shift based on the patient's particular issues in addressing HIV risk: 1. Enhance self-perception of risk; 2. Address dissonance (examples when beliefs and behavior are at odds) and ambivalence (mixed feelings) about risk reduction; 3. Increase self-efficacy (belief in one's power or ability to do something); 4. Invoke peer and community norms. The patient's presence in the clinic and request for STD services is the starting point from which the counselor addresses these issues.

In this section, the counselor is attempting to use the patient's STD concerns to encourage him/her to examine HIV issues. The link between STD and HIV risk should be explicitly emphasized. The process is intended to help the patient become motivated and invested in addressing HIV issues and concerns with the counselor. At the completion of this component of the session, the counselor's aim is to have the patient fully engaged in the session and invested in reducing HIV/STD risk.

## **C. Explore the Specifics of Most Recent Risk Incident (2-3)**

The counselor should have an open and inquisitive approach to this portion of the session. This approach will stimulate the patient's curiosity and encourage him/her to self-reflect and examine his/her own behaviors. The exploration of the risk behavior should be specific. A thorough discussion of the most recent risk behavior may help the patient clarify how the risk behavior occurred. What may have initially seemed like an accident or an unusual incident begins to have concrete circumstances that contributed to the patient's decision to engage in high-risk behavior. This process can demystify the risk behavior for the patient.

The questions asked by the counselor are directed at eliciting the entire range of factors that may have contributed to the risk behavior. The counselor should be aware that emotions, recent life events, substance use, self-esteem, and other patient characteristics and issues may influence a particular risk incident or pattern of risk behavior.

The counselor and patient should be working together to understand the context of the risk behavior. If the patient's risk behavior is episodic or chronic, the counselor is attempting to discover the factors that contribute to this pattern of risk behavior.

## **D. Review Previous Risk Reduction Experiences (2-4)**

The counselor should explore any changes initiated by the patient to reduce his/her HIV risk(s). This provides the counselor with an essential opportunity to support and reinforce the patient. The counselor should note all of the patient's intentions, communication and actions concerning HIV risk reduction. The counselor should elicit obstacles encountered by the patient in considering or attempting behavior change. The counselor should gently and sensitively discuss the challenges the patient has encountered or perceived.

It is important to acknowledge that behavior change is a complex, difficult, and challenging process. It is helpful, particularly if the patient has difficulty articulating his experiences with risk reduction, to explore his/her perception of community and peer norms concerning HIV prevention. Further, encouraging the patient to articulate his/her attitudes and beliefs about HIV risk behavior may provide additional insight. This process allows the patient to verbalize the extent to which he/she has addressed HIV issues and provides the counselor with insight into the patient's strengths and difficulties in initiating and sustaining behavior change. During this portion of the session the counselor may educate and clarify misinformation for the patient, as needed.

#### **E. Synthesis of Risk Incident and Risk Pattern (2-4)**

The purpose of this component of the session is to enable the patient to gain an understanding of the complexity of factors that influence his/her risk behavior. The counselor summarizes the inter-related factors influencing the patient's risk behavior. This summary provides the patient with an organized perspective of his/her narrative. The counselor's approach to this should be empathic and non-judgmental, which will help the patient understand his/her own behavior with compassion. This process enhances the counselor and patient collaboration in reducing the patient's risk of acquiring HIV/STD.

It may seem paradoxical, but the counselor must simultaneously convey a sense of urgency in understanding this behavior and be clear about the consequences should the patient fail to prioritize and respond to this situation. This component of the session provides the foundation on which the risk reduction plan will be developed. The counselor will reference the highlights of this summary during test result and risk reduction component of the session.

At the conclusion of this component, the patient is directed to the STD clinician or to the waiting room to resume his/her position in the queue.

### **II. Post-Test Counseling**

#### **F1. Provide Rapid Test Results - NEGATIVE (1-2)**

The counselor should provide the initial test result in simple terms, avoiding technical jargon. The patient may be very relieved at receiving the negative test result. The counselor should allow the patient to experience his/her pleasure at not being infected while gently underscoring the need for behavior change in order for the patient to remain negative. The counselor should cautiously explore feelings and beliefs the patient has about his/her negative test results, particularly in the context of the risk behavior the patient has described thus far in the session.

The counselor should be alert to the possibility that the patient may experience some dis-inhibition (i.e., feel more inclined to engage in risky behavior) in response to the results. The patient may believe the test result is an indication that he/she has, thus far, made the “right choices.” It is often helpful for the counselor to underscore the fact that the negative test result does not indicate that the patient’s sex/needle-share partner(s) are not infected.

There is a slight possibility that a recent risk behavior (especially in the last month) may have resulted in the patient becoming infected without the infection being indicated in this test result. However, both counselor and patient should be reminded that the current result represents all other, sometimes years’, previous risk behavior.

Counselors must be very careful with their “retest message.” If there is not a significant risk in the previous 3 months, then no additional test is indicated unless the patient has a later exposure to HIV. If there is a very recent and significant risk exposure, there is a small chance that the patient could have been infected by that exposure. The counselor should remember that the risk of infection from a single exposure, when the partner is known to be infected, is relatively small (<1 – 8%).

The counselor should avoid technical discussions of this information and recommend, when necessary, a specific time for possible retest linked to a specific previous date of exposure. In summary, a brief explanation of the possible need for retesting is sometimes, with some patients, important, but this should not be over-emphasized. Too much attention to retesting takes away attention from the risk reduction process and often inaccurately diminishes the meaning of the HIV negative result.

## **F2. Provide Test Results – PRELIMINARY POSITIVE (5-10)**

The priority for this component of the session is to ensure that the patient correctly understands the test result. The counselor should provide the initial test result in simple terms, avoiding technical jargon. The counselor should choose language that reflects the likelihood that the patient is actually infected with HIV.

In choosing phrases to convey the meaning of the initial test result, the counselor should consider the patient’s reported risk behavior. The counselor should be clear with the patient that the information provided by the patient in the beginning of the session, particularly the risk assessment, may help influence the patient and counselor’s understanding of the results. This may provoke the patient to offer additional details concerning risk that he/she was reluctant to address previously.

The counselor should remind the patient that this result is preliminary and review the process of supplemental testing. The counselor must emphasize the need for supplemental testing, as well as the importance of the patient returning for additional results, and identify sources of support while awaiting test results. The counselor should acknowledge that receiving this initial result can be disconcerting, elicit feedback from the patient as to how he/she is feeling about the result, and provide appropriate support.

#### **G. Negotiate Risk Reduction Plan (4-5)**

The risk reduction plan is a fundamental component of the prevention counseling session. The counselor should assist the patient in identifying a behavior that corresponds to his/her risk and that he/she is invested in changing. It is essential that the plan match the patient's skills and abilities with his/her motivation to change a specific behavior. The counselor should challenge the patient to go beyond what he/she has previously attempted in terms of risk reduction. The plan must be specific in that it describes the who, what, where, when and how of the risk reduction process. It must be concrete in that it details the successive actions required of the patient to implement and complete the risk reduction plan. Finally, it must be incremental in that it is directed at a single aspect of the risk behavior or one particular factor/issue that contributes to that risk behavior.

The counselor should avoid supporting risk reduction plans that involve unreasonable or radical changes in the patient's life. The patient may experience a "flight to health" as a result of the STD clinic experience, the anxiety from the testing process, or the quality of the counseling interaction. Global risk reduction messages such as "always wear condoms," "remain monogamous," or "abstain from sex" do not meet the criteria for an appropriate risk reduction plan.

The counselor should ensure that the patient agrees with the plan and is committed to its implementation. The patient should be asked to critique the plan and identify problems with the plan. The counselor may even quiz the patient on the plan or provide plausible examples of obstacles the patient may encounter in initiating the plan. These obstacles should be problem-solved with the patient and may require revising the plan. The process of developing a plan represents the patient's movement toward risk reduction.

#### **H. Identify Sources of Support and Provide Additional Referrals (3-4)**

This component of the session is intended to identify or develop for the patient peer and community support for HIV risk reduction, as well as to provide referral to professional services directed at addressing specific issues the patient may have identified. The priority of this component of the session is to identify a specific friend or relative with whom the patient will discuss his/her risk reduction plan and report to regarding the implementation and completion of the plan. This step is critical because in the rapid test scenario there is no second session for the counselor to review with the patient his/her experience in implementing the plan.

The process of the patient checking in with someone about the plan is important because it gives enhanced meaning to the plan and increases the patient's personal expectations about completing the plan. The patient must trust this person and feel comfortable with his/her ability to keep the patient's confidence. It is reasonable that the trusted person be the same person with whom the patient is trying to initiate the behavior change plan.

The counselor should discuss the process of confiding the risk reduction plan with a similar level of detail as that devoted to developing the plan. The counselor and patient should establish a time frame during which this will occur. When will the patient disclose the plan to this person? When will the patient report the progress or completion of the plan to this person?

If during the course of the session the counselor or patient has identified a need for referrals to professional services (e.g., drug treatment, support group, mental health counseling, etc.), then counselor should be prepared to provide specific provider names and phone numbers to the patient. Referrals in this context are particularly important to the extent that the referral services received by the patient may complement or enhance the risk reduction process. The counselor should confirm that the referral is something the patient is willing to consider using.

To the extent possible, the counselor should try to provide referrals consistent with that patient's readiness to receive the services, comfort with the setting in which the service is provided, and interest in accessing the services. The counselor should be cautious not to overwhelm the patient with numerous referrals. A single appropriate referral is often better than several referrals to generic types of support services. The referral may augment the risk reduction plan, but unless it is the only alternative, completion of the referral by the patient should not be the primary objective of the risk reduction plan.

#### **I. Provide Appointment Card/Reminder for Follow-up (1-2)**

For HIV negative patients, the counselor should encourage follow-through on risk reduction plan. For patients initially testing preliminary positive, the counselor should ensure the patient will return to the clinic for supplemental confirmatory test results.



# HIV TEST FORM PART 1

Form Approved OMB No. 0820-0696, Exp. Date: 06/31/2010

## GENERAL INSTRUCTIONS FOR COMPLETING THE HIV TEST FORM

- This form is designed to be read by an Optical Character Recognition (OCR) scanner. The legibility of this form depends on the quality of the hand-written and selected information.
- Carefully separate the sheets at the perforations. If the form tears, it may not be readable by the scanner or operator.
- Each part has a top sheet and a bottom carbonless copy. The top copy (white) is the only sheet that should be scanned. The bottom copy (yellow) should **NOT** be scanned; rather it should be used for record keeping purposes.
- **DO NOT** use red ink. Blue or black ink is preferred.
- **DO NOT** fold, staple, wrinkle or tear form(s).
- **DO NOT USE WHITE OUT.** White out sometimes will cause a mis-read by the scanning software.
- **DO NOT** mark on the bar codes of the Form ID numbers. Marking on the Form ID numbers (barcode) may cause the wrong number to be scanned.
- **DO NOT** make any stray marks on the form(s), particularly in the fields where answers will appear.
- Part 1 is the only form with a pre-printed code. You must attach a form identification sticker (barcode) located on the back of the carbonless copy (yellow) to Part 2 and/or Part 3 in order to link a client's information.
  - Part 1 should be used for all testing events
  - Part 2 should be used to record referral data on **confirmed HIV positive** clients
  - Part 3 is used by jurisdictions funded to collect HIV Incidence data.

## RESPONSE FORMATS

There are three different response formats on the form that you will use to record data: (1) text boxes, (2) check boxes, and (3) radio buttons. Instructions for each one of these formats are listed below.

### Text boxes

Text boxes are used to record handwritten information (e.g., codes, dates). When writing letters or numbers in the boxes:

- use all capital letters and write neatly in your best penmanship. **DO NOT** use cursive.
- put only 1 letter or number per box and **DO NOT** have any part of the letter or number touch the edges of the box.

Here are examples of how to write letters and numbers:

### LETTERS

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

### NUMBERS

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

### Check boxes

Check boxes are used to select all options that apply. For example, check boxes are used to record information about "Race."

- use an "X" instead of a check mark because the tail of the check mark might run over into another box.
- keep the "X" within the edge of the box.

### Radio buttons

Radio buttons are ovals used to select only one option from among two or more options. For example, radio buttons are used to select "Current Gender." When selecting an option using a radio button:

- fill in the oval completely.
- **DO NOT** mark over area of the oval.





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**HIV TEST FORM****PART 1**

Form Approved: OMB No. 0920-0696, Exp. Date: 08/31/2010



Agency		Session Date (MMDDYYYY)		Unique Agency ID Number		Intervention ID	
Site ID		Site Type		Site Zip Code			
Client ID		Date of Birth (MMDDYYYY)		State		County	
Zip Code							
Ethnicity		Race — Check all that apply		Current Gender		Previous HIV Test?	
Self-Reported Result							
Provide date of last test (MMYYYY)							
Sample Date (MMDDYYYY)		Worker ID					
Test Election		Tested anonymously		Tested confidentially		Declined testing	
Test Technology		Conventional		Rapid		Other	
Specimen Type		Blood: finger stick		Blood: venipuncture		Blood spot	
Test Result		Positive/Reactive		Indeterminate		NAAT-pos	
Result Provided		Yes		No			
Date Provided (MMDDYYYY)							
If results not provided, why?		Declined notification		Did not return/Could not locate		Obtained results from another agency	
If rapid reactive, did client provide confirmatory sample?		Yes		Client declined confirmatory test		Did not return/Could not locate	
Referred to another agency		Other					
Choose one if:		Client was not asked about risk factors		Client was asked, but no risk was identified		Client declined to discuss risk factors	
If client risk factor information was discussed, please mark all that apply:		In past 12 months has client had:		...without using a condom?		Injection Drug Use (IDU)	
Vaginal or Anal Sex		Oral Sex		...with person who is an IDU?		Has client used injection drugs in past 12 months?	
With Male		With Female		...with person who is MSM? (Female Only)		Did client share drug injection equipment?	
...with person who is HIV positive?							
Session Activity		Local Use Fields		CDC Use Fields			
During this visit, was a risk reduction plan developed for the client?		L1		C1			
Other Session Activities (see codes on reverse)		L2		C2			

Public reporting burden of this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-79, Atlanta, Georgia 30333; ATTN: PRA 0920-0696.

WHITE COPY = Scan

YELLOW COPY = Record Keeping

CDC 50.135a (E), 10/2007



**Client Identifying Data (Optional)**

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Other: \_\_\_\_\_

**Codes for Site Type**

F01 Inpatient Facility  
 F01.01 Inpatient Hospital  
 F01.50 Inpatient- Drug / Alcohol Treatment  
 F01.88 In patient Facility- Other  
 F01.99 Inpatient Facility- Unknown  
 F02 Outpatient facility  
 F02.03 Outpatient- Private Medical Practice  
 F02.04 Outpatient- HIV Specialty Clinic  
 F02.10 Outpatient- Prenatal/ OBGYN Clinic  
 F02.12 Outpatient- TB Clinic  
 F02.19 Outpatient- Drug / Alcohol Treatment Clinic  
 F02.20 Outpatient- Family Planning  
 F02.30 Outpatient- Community Mental Health  
 F02.51 Outpatient- Community Health Clinic  
 F02.58 Outpatient- School/University Clinic  
 F02.60 Outpatient- Health Department/Public Health Clinic  
 F02.61 Outpatient- Health Department/Public Health Clinic-HIV  
 F02.62 Outpatient- Health Department/Public Health Clinic-STD  
 F02.88 Outpatient Facility- Other

F02.99 Outpatient Facility- Unknown  
 F03 Emergency Room  
 F04.01 Blood Bank, Plasma Center  
 F04.05 HIV Counseling and Testing Site  
 F06 Community Setting  
 F06.01 Community Setting – AIDS Service Organization – non clinical  
 F06.02 Community Setting – School/Education Facility  
 F06.03 Community Setting – Church/Mosque/Synagogue/Temple  
 F06.04 Community Setting – Shelter/Transitional housing  
 F06.05 Community Setting – Commercial  
 F06.06 Community Setting – Residential  
 F06.07 Community Setting – Bar/Club/Adult Entertainment  
 F06.08 Community Setting – Public Area  
 F06.09 Community Setting – Workplace  
 F06.12 Individual Residence  
 F06.10 Community Setting – Community Center  
 F06.88 Community Setting – Other  
 F07 Correctional Facility  
 F88 Facility – Other

**Codes for Other Risk factor(s)**

01 Exchange sex for drugs/money/or something they need  
 02 While intoxicated and/or high on drugs  
 05 With person of unknown HIV status  
 06 With person who exchanges sex for drugs/money  
 08 With anonymous partner  
 09 With person who has hemophilia or transfusion/transplant recipient  
 11 Sex with transgender

**Codes for Other Session Activities**

03.00 HIV Testing  
 04.00 Referral  
 05.00 Personalized Risk assessment  
 06.00 Elicit Partners  
 07.00 Notification of exposure  
 08.01 Information – HIV/AIDS transmission  
 08.02 Information-Abstinence/postpone sexual activity  
 08.03 Information-Other sexually transmitted diseases  
 08.04 Information-Viral hepatitis  
 08.05 Information – Availability of HIV/STD counseling and testing  
 08.06 Information-Availability of partner notification and referral services  
 08.07 Information – Living with HIV/AIDS  
 08.08 Information – Availability of social services  
 08.09 Information – Availability of medical services  
 08.10 Information – Sexual risk reduction  
 08.11 Information – IDU risk reduction  
 08.12 Information – IDU risk free behavior  
 08.13 Information – Condom/barrier use  
 08.14 Information – Negotiation / Communication  
 08.15 Information – Decision making  
 08.16 Information – Disclosure of HIV status  
 08.17 Information – Providing prevention services  
 08.18 Information – HIV testing  
 08.19 Information – Partner notification  
 08.20 Information – HIV medication therapy adherence  
 08.21 Information – Alcohol and drug use prevention  
 08.22 Information – Sexual health  
 08.23 Information – TB testing  
 08.66 Information – Other  
 09.01 Demonstration – Condom/barrier use  
 09.02 Demonstration – IDU risk reduction  
 09.03 Demonstration – Negotiation / Communication  
 09.04 Demonstration – Decision making  
 09.05 Demonstration – Disclosure of HIV status  
 09.06 Demonstration – Providing prevention services  
 09.07 Demonstration – Partner notification  
 09.66 Demonstration – Other  
 10.01 Practice – Condom/barrier use  
 10.02 Practice – IDU risk reduction  
 10.03 Practice – Negotiation / Communication  
 10.04 Practice – Decision making  
 10.05 Practice – Disclosure of HIV status  
 10.06 Practice – Providing prevention services

10.07 Practice – Partner notification  
 10.66 Practice – Other  
 11.01 Discussion – IDU risk reduction  
 11.02 Discussion – IDU risk reduction  
 11.03 Discussion – HIV testing  
 11.04 Discussion – Other sexually transmitted diseases  
 11.05 Discussion – Disclosure of HIV status  
 11.06 Discussion – Partner notification  
 11.07 Discussion – HIV medication therapy adherence  
 11.08 Discussion – Abstinence/postpone sexual activity  
 11.09 Discussion – IDU risk free behavior  
 11.10 Discussion – HIV/AIDS transmission  
 11.11 Discussion – Viral hepatitis  
 11.12 Discussion – Living with HIV/AIDS  
 11.13 Discussion – Availability of HIV/AIDS counseling testing  
 11.14 Discussion – Availability of partner notification and referral services  
 11.15 Discussion – Availability of social services  
 11.16 Discussion – Availability of medical services  
 11.17 Discussion – Condom/barrier use  
 11.18 Discussion – Negotiation / Communication  
 11.19 Discussion – Decision making  
 11.20 Discussion – Providing prevention services  
 11.21 Discussion – Alcohol and drug use prevention  
 11.22 Discussion – Sexual health  
 11.23 Discussion – TB testing  
 11.66 Discussion – Other  
 12.01 Other testing – Pregnancy  
 12.02 Other testing – STD  
 12.03 Other testing – Viral hepatitis  
 12.04 Other testing – TB  
 13.01 Distribution – Male condoms  
 13.02 Distribution – Female condoms  
 13.03 Distribution – Safe sex kits  
 13.04 Distribution – Safer injection / bleach kits  
 13.05 Distribution – Lubricants  
 13.06 Distribution – Education materials  
 13.07 Distribution – Referral lists  
 13.08 Distribution – Role model stories  
 13.66 Distribution – Other  
 14.01 Post-intervention follow up  
 14.02 Post-intervention booster session  
 15.00 HIV Testing History Survey  
 88 Other

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## **OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Procedure With Oral Fluid and Fingerstick Whole Blood Specimens**

### **I. Summary & Principle of the Test**

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using a Western blot test. Results are typically reported within hours to weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HIV diagnosis. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This Rapid HIV test provides results with greater than 99% accuracy in as little as 20 minutes from an oral fluid or fingerstick whole blood sample.

Using a rapid HIV test increases the number of HIV-infected persons who may be diagnosed. The Centers for Disease Control and Prevention (CDC) estimates that nearly twenty-one percent of the estimated 1,100,000 HIV-infected persons in the United States do not know their HIV status. As a result, they cannot benefit from early intervention with effective antiviral therapy. Rapid HIV testing addresses this issue by providing results during the initial visit and enabling immediate counseling. Additionally, for pregnant women who do not know their HIV status at the time of delivery, rapid HIV testing permits therapy to be initiated for these mothers during labor, and to their infants postpartum, substantially reducing the chance that the infants will become infected with HIV. Likewise, rapid HIV testing is instrumental in the decision to initiate treatment for health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 “needlestick injuries” occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results.

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results. The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region in the Test (T) zone and a goat anti-human IgG in the Control (C) zone immobilized onto a nitrocellulose membrane.

An oral fluid specimen is collected using the flat pad on the test device, followed by the insertion of the test device into the vial of developer solution. A fingerstick whole blood specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it re-hydrates the protein-A gold colorimetric reagent contained in the device. As specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen. Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1 and/or HIV-2.

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen.

## **II. Specimen**

Oral fluid or whole blood obtained by fingerstick procedure (see **Fingerstick Blood Collection procedure**)

## **III. Materials**

- A. Materials required but not supplied with kit
  - 1. Timer/ Stop Watch (20-40 min)
  - 2. Clean, disposable, absorbent workspace cover
  - 3. Biohazard disposal container
- B. Additional materials required for fingerstick specimens
  - 1. Lancet
  - 2. Sterile gauze pad
  - 3. Antiseptic wipe
  - 4. Latex, vinyl or nitril disposable glove (optional for oral fluid testing)
- C. Materials supplied in kit
  - 1. Test device: A single use
  - 2. Absorbent Packet
  - 3. Developer solution vial
  - 4. Reusable Test Stand
  - 5. Specimen Collection Loops
  - 6. Subject information Pamphlets
  - 7. Package insert
- D. Storage

Store unused OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Tests unopened at 2°-27°C (35-80° F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature 15° -37°C (59-99° F) before opening.

#### IV. Safety

- A. Handle specimens and materials contacting specimens as if capable of transmitting infectious agents.
- B. Do not drink, eat, or smoke in areas where specimens are being handled.
- C. Wear a lab coat, eye protection and disposable gloves while handling blood specimens. Change gloves and wash hands thoroughly after performing each test.
- D. Dispose of gloves in a biohazard waste container after use.
- E. Oral fluid is not considered potentially infectious unless it contains blood. Use of gloves for oral fluid is optional. Test administrators with breaks in the skin (cuts, abrasions, or dermatitis) should wear gloves when performing oral fluid testing. Wash hand thoroughly after performing each oral fluid test and after contact with oral fluid.
- F. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.
- G. Lancets should be placed in a puncture-resistant container prior to disposal.
- H. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants.
- I. A solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.
- J. **NOTE: Do not autoclave solutions that contain bleach.** For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings".<sup>5</sup>
- K. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.

#### V. General Test Preparation

- A. Set up your Workspace
  - 1. Gather the materials you will need for either an oral fluid collection or a fingerstick whole blood collection.
  - 2. This test should be performed at operating temperature 15°-37°C (59°-99°F). If the Divided Pouch containing the Test Device and Developer Solution Vial is not at operating temperature, allow time for the Pouch to come to operating temperature before removing the contents from its wrapper.
  - 3. Review specimen collection instructions.
  - 4. Refer to the *External Quality Control* section of the OraQuick ADVANCE® HIV-1/2 Rapid Antibody Test package insert to determine when Kit Controls should be run.
  - 5. Cover your workspace with a clean, disposable, absorbent workspace cover.
  - 6. Place the Reusable Test Stand on a flat, level surface. Use only the stand provided.
  - 7. Give the client the "Subject Information" pamphlet provided with the kit before collecting specimen. (See **Pre-Test Screening** procedure)

B. General Test Preparation

1. Using the notched corners, tear the top of each end of the Divided Pouch containing the Test Device and Developer Solution Vial. To prevent contamination, leave the Test Device in the Divided Pouch until needed.
2. Remove the Developer Solution Vial from the Divided Pouch. Firmly holding the Developer Solution Vial, carefully uncap the vial by gently rocking the cap back and forth. Set the cap on your workspace cover. Slide the uncapped Developer Solution Vial into the top of the slot in the angled Reusable Test Stand, making sure the vial is completely seated in the stand.
3. DO NOT force the vial into the stand from the front of the slot, as splashing may occur.
4. DO NOT touch the Flat Pad.
5. Check to see if an Absorbent Packet is present. If no Absorbent Packet is present, discard the Test Device and obtain a new Divided Pouch for testing.

C. Testing Procedure - Oral Fluid

1. If tests are performed on more than one client at one time label the Developer Vial either with the sticker or sharpie pen appropriately. **NOTE: DO NOT cover the two holes on back of the Test Device with labels or other materials. Doing so may cause an Invalid result.**
2. Ensure prior to testing that the person has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the person wait for at least 30 minutes prior to testing if they have used any oral care products.
3. Have the person being tested remove the Test Device from its Pouch. **DO NOT** allow the person to touch the Flat Pad. Check to make sure that an Absorbent Packet is included with the Test Device. If no Absorbent Packet is present, discard the Test Device and obtain a new Divided Pouch for testing.
4. Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad. **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. **NOTE:** Both sides of the Flat Pad may be used during this procedure.
5. Insert the Flat Pad of the Test Device all the way into the Developer Solution Vial. Make sure the Flat Pad touches the bottom of the Developer Solution Vial. The Result Window should be facing towards you.
6. Start timing the test. **DO NOT** remove the Test Device from the Developer Solution Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops. Read the results at 20 minutes but not more than 40 minutes in a fully lighted area.
7. Read the results: Note whether there is a band opposite the "C" and "T" area.



8. After recording the results, dispose of the used Developer Solution Vial and the Test Device in an appropriate waste container. OSHA Guidelines do not require disposal in a biohazardous waste container unless blood is present in the sample.
9. Follow CDC guidelines to inform the test subject of the test result and its interpretation.<sup>6</sup>

D. Testing Procedure - Fingerstick Whole Blood

1. If tests are performed on more than one client at one time label the Developer Vial either with the sticker or sharpie pen appropriately. **NOTE: DO NOT cover the two holes on back of the Device with labels or other materials. Doing so may cause an Invalid result.**
2. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
3. Pick up an unused Specimen Collection Loop by the thick 'handle' end. Touch the round end of an unused Specimen Collection Loop to the drop of blood. Visually inspect the Loop to make sure that it is completely filled with blood. **NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.
4. Immediately immerse the blood-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard the used loop in a biohazard waste container.
5. Examine the solution in the Developer Solution Vial to ensure that it appears pink, indicating that the blood specimen was properly introduced. If the developer solution is not pink after adding the specimen, discard the Developer Solution Vial as infectious waste, open a new Divided Pouch, and collect a new specimen.
6. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial.**
7. **DO NOT** cover the two holes in the back of the Test Device after placing it into the Developer Solution. Doing so may cause an invalid result.
8. Start timing the test. **DO NOT** remove the Test Device from the Developer Solution Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops. Read the results at 20 minutes but not more than 40 minutes in a fully lighted area.
9. Read the results: Note whether there is a band opposite the "C" and "T" area.



10. After recording the results, dispose of the used Developer Solution Vial and the Test Device in a biohazard waste container.
11. Follow CDC guidelines to inform the test subject of the test result and its interpretation.<sup>6</sup>

E. Reading the Test

1. Sample of a **Non-Reactive** (negative) Result: (see Fig. 1 below)
  - Only the control (C) area shows a line.
  - No line is present in the test (T) area.
  - Test result interpreted as **NEGATIVE FOR HIV-1 and/or HIV-2 Antibodies.**



Fig. 1

2. Sample of a **Reactive** (positive) Result: (see Fig. 2 below)
  - Lines appear in both the control (C) and the test (T) areas.
  - Reactive results must be confirmed.
  - Test result interpreted as **PRELIMINARY POSITIVE FOR HIV-1 and/or HIV-2 Antibodies.**



Fig. 2

3. Sample of **Invalid** Result: (see Fig. 3 below)
  - **No line** is present in the area adjacent to either the “C” or “T” triangle.
  - A line appears opposite the “T” triangle but not the “C” triangle.
  - A red background in the result window makes it difficult to read the results after 20 minutes.
  - A line appears, but not opposite the “C” (or “T”) triangle - misalignment.



Fig. 3

- F. Clinical Results Interpretation
  1. **Non-Reactive** (Negative): These individuals are not infected except for those who have had a recent (within 3 months) known or a possible exposure to HIV. Recommend a retest for clients with a recent exposure. (See **Rapid Testing Counseling Protocol**)
  2. **Reactive** (Preliminary Positive) Test: Further testing is always required to confirm a reactive screening test result. Convey this information like this: *“Your preliminary test result was positive, but we won’t know for sure if you are HIV-infected until we get the results from your confirmatory test”*. The client must be instructed to avoid transmission of virus. It is essential to explain:
    - The meaning of reactive screening test result in simple terms, avoiding technical jargon.
    - Emphasize the importance of confirmatory testing and schedule a return visit for confirmatory test results.
    - Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing. (See **Rapid Testing Counseling Protocol**)

## VI. Quality Control

### A. Controls

Positive and negative controls (human plasma-based reagents) are supplied with the kit. These kit controls verify that the test is working properly. These are negative for Hepatitis B and Hepatitis C antibodies.

B. Frequency of Controls

1. Commercial positive and negative controls should be run under the following circumstances:
  - Each new operator prior to performing testing on patient specimens
  - When opening a new test kit lot
  - Whenever a new shipment of test kits is received
  - If the temperature of the test kit storage area falls outside of 2-27°C (35-80°F)
  - If the temperature of the testing area falls outside of 15-37°C (59-99°F)
  - At periodic intervals as dictated by the user facility.

C. Use

Store the OraQuick *ADVANCE*® Test Kit Controls at 2-8°C. Do not use controls past the expiration date printed on the outer carton. Open kit control vials only when you are performing tests. Recap and store the vials in their original container at 2-8°C after use. Opened vials expire 8 weeks after they are put in use. Do not use controls if the reagent appears visually cloudy or discolored.

D. Expected Values

1. Positive control: both the control region and test region will show a line. (see Fig. 2)
2. Negative control: only the control region will turn color, the test region will **not** show a line. (see Fig. 1)

E. Quality Control Records

Quality Control (QC) information is to be recorded on the appropriate QC Log Sheet (attached). The information required includes Name of test, site performed, date, time and person performing the test, lot numbers of all reagents, expiration dates of all reagents, expected results and observed results.

F. Corrective Action

1. If the controls fail to yield the expected results, **DO NOT** perform any patient testing until performance issues are resolved and expected results are obtained and recorded.
2. Document the corrective action taken.

(See the **CDC Quality Assurance Guidelines**)

## **VII. Test Limitations**

- A. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test must be used in accordance with the instructions in the package insert of the device to obtain an accurate result.
- B. FDA and CDC classify this procedure as a waived procedure for oral fluid, fingerstick whole blood and venipuncture whole blood. Plasma specimens are classified as moderately complex. However, the CLIA-waived procedure must be performed by persons who have received appropriate training and their competency is documented.
- C. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
- D. FDA approves this test for use with oral fluid, fingerstick and venipuncture whole blood, and plasma specimens only. Use of other types of specimens may not yield accurate results. Clinical data is has not been collected to demonstrate the performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 in persons under age of 12.
- E. A Reactive result using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
- F. For a Reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
- G. For a fingerstick whole blood collection, when an insufficient amount of blood has been added to the test device, the control band will not appear on the membrane. An additional prick may be required and use a new device. If the control band still fails to appear, the test should be terminated since deterioration of the test cassette may have occurred. Report the matter to the laboratory director.
- H. A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels. Rule out a history of exposure to HIV within 3 months. Recommend a retest for clients with a recent exposure.

### VIII. References

1. Gallo RC, Salahuddin SZ, Popovic M, et al. Frequent detection and isolation of cytopathic retroviruses (HTLV III) from patients with AIDS and at risk for AIDS. *Science* 1984; 224:500-3.
2. Curran JW, Morgan WM, Hardy AM, et al. The epidemiology of AIDS: current status and future prospects. *Science* 1985; 229:1352-7.
3. Clavel F, Guetard D, Brun-Vezinet F, et al. Isolation of a new human retrovirus from West African patients with AIDS. *Science* 1986; 233:343-6.
4. Schulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. *Appl Env Microbiol* 1981; 42:762-7.
5. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988; 37(24):377-388.
6. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR* 2006; 55(RR14):1-17.
7. Package Insert. 2007. OraSure Technologies Inc. Bethlehem PA 18015.
8. Michigan Department of Community Health, *Rapid HIV Testing-OraQuick®*, January 2003.

# A Quick Reference Listing for Clinicians and Health care Professionals to State HIV Testing Laws<sup>1</sup>

- > This Quick Reference Listing for clinicians and health care professionals is a summary of relevant state HIV testing laws. Please refer to your individual state link for updates that may have occurred since this listing as of February 4, 2011.

## Alabama

### Informed Consent

Informed consent required: general consent may be used (see State Policies Relating to HIV Testing, 2011, in the individual state profile). Compatible with CDC Recommendations and Guidelines.

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - rapid testing may be used on pregnant women presenting to labor and delivery. A confirmatory test is required before notifying the patient of HIV test results.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of a possible exposure to HIV is required.

### Minor/Adolescent Testing

Persons 12 years of age or older may consent to STD testing, HIV not explicitly included.

### Recommended Resources

Code of Alabama - <http://www.legislature.state.al.us/CodeofAlabama/1975/coatoc.htm>

## Alaska

### Informed Consent

No specific provisions regarding informed consent were found.

### Counseling

Post-test counseling (regarding measures for preventing transmission and the need for treatment) is required for individuals who have been or may have been exposed.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to medical services, HIV not explicitly included.

### Recommended Resources

Alaska Legislature - <http://www.legis.state.ak.us/folhome.htm>

## Arizona

### Informed Consent

Oral or written informed consent is required; opt-out process is implied; compatible with CDC Recommendations and Guidelines.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - consent form must inform patient of availability of anonymous testing. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners and needle-sharing partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included.

### Recommended Resources

Arizona Revised Statutes - <http://www.azleg.state.az.us/ArizonaRevisedStatutes.htm>

## Arkansas

### Informed Consent

Informed consent is not required for diagnosis (see State Policies Relating to HIV Testing, 2011, in the individual state profile). Informed consent is not specified for screening. Compatible with CDC Recommendations and Guidelines.

### Counseling

Counseling must be offered in cases of health care worker exposure.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included.

### Recommended Resources

Arkansas Department of Health - <http://www.healthysarkansas.com>

## California

### Informed Consent

Specific simple consent through the opt-out process required (see State Policies Relating to HIV Testing, 2011, for exceptions); written not required. Consistent with CDC Recommendations and Guidelines.

### Counseling

Counseling must be offered to a patient with a confirmed HIV positive test. Counseling must be offered to notified partners and contacts.

### Provisos of Testing

- Anonymous - testing must be made anonymously. Anonymous testing is available at designated anonymous testing sites.
- Rapid - HIV counselors may perform an HIV test if authorized under a physician/surgeon, trained, and meets other requirements (see State Policies Relating to HIV Testing 2011). Patients must be informed that the preliminary result of the test is indicative of the likelihood of HIV infection and that the result must be confirmed by an additional more specific test, or, if approved by the CDC, a second different rapid HIV test.
- Routine - as part of consent, a medical provider must inform the patient that in cases of negative results, routine testing is advised.

### Disclosure

Notification to sexual partners and needle-sharing partners of possible exposure to HIV to required.

### Minor/Adolescent Testing

Persons 12 years of age or older may consent to HIV testing and treatment.

### Recommended Resources

California Code of Regulations - <http://www.calregs.com/linkedslice/default.asp?SP=CCR-1000&Action=Welcome>  
California Legislative Information - <http://www.leginfo.ca.gov>

## Colorado

### Informed Consent

Informed consent is required (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions); oral or written not specified. Opt-in or opt-out process not specified. Compatible with CDC Recommendations and Guidelines.

### Counseling

Post-test counseling is required with HIV positive test results. Counseling must be offered in cases of health care worker exposure.

### Provisos of Testing

- Anonymous - testing must be made available anonymously. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contact were found.

### Minor/Adolescent Testing

Minors may consent to HIV testing and treatment. Physicians may, but are not required to, notify parents of the HIV test result.

### Recommended Resources

Colorado Revised Statutes - <http://www2.michie.com/colorado/lpext.dll?f=templates&fn=fs-main.htm&2.0>



## Connecticut

### Informed Consent

General consent for medical care is sufficient; declination must be documented in the medical record (see State Policies Relating to HIV Testing, 2011, for exceptions).

### Counseling

Post-test counseling or referral for counseling as needed.

### Provisos of Testing

- Anonymous - consent form must inform patient of the availability of anonymous testing.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners is not required.

### Minor/Adolescent Testing

Minors may consent to HIV testing.

### Recommended Resources

General Statutes of Connecticut - <http://www.cga.ct.gov/asp/menu/Statutes.asp>

## Delaware

### Informed Consent

Specific informed consent required; may be oral or in writing.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Persons 12 years of age or older may consent to HIV testing and treatment.

### Recommended Resources

Delaware Administrative Code - <http://www.state.de.us/research/AdminCode/>

## District of Columbia

### Informed Consent

No specific provisions regarding informed consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - testing must be made available anonymously. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding disclosure were found.

### Minor/Adolescent Testing

No specific provisions regarding minor or adolescent testing were found.

### Recommended Resources

DC Department of Health, HIV/AIDS Administration -  
[http://doh.dc.gov/doh/cwp/view,a,1371,q,573205,dohNAV\\_GID,1802,dohNav,\[33200\]34259|.asp](http://doh.dc.gov/doh/cwp/view,a,1371,q,573205,dohNAV_GID,1802,dohNav,[33200]34259|.asp)

## Florida

### Informed Consent

Informed consent required; may be oral or in writing.

### Counseling

Counseling must be offered.

### Provisos of Testing

- Anonymous - testing must be made available anonymous. Physicians must inform patients of availability of anonymous testing.
- Rapid - a confirmatory test is required before notifying the patient of HIV test results.
- Routine - protocols must be made available by the Department of health care providers for offering HIV testing, on a voluntary basis, as a routine part of primary health care or admission to a health care facility.

### Disclosure

No specific provisions regarding disclosure were found.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV is explicitly included.

### Recommended Resources

Online Sunshine: Florida Legislature, Statutes and Constitution -  
<http://www.leg.state.fl.us/Statutes/index.cfm?Tab=statutes&submenu-1>  
Florida Department of Health - <http://www.doh.state.fl.us/>

## Georgia

### Informed Consent

Consent is required; oral or written not specified.

### Counseling

Pre-test counseling and post-test medically appropriate counseling with confirmed HIV positive test result are required. Counseling of the spouse of HIV positive patient is required.

### Provisos of Testing

- Anonymous - testing must be made available anonymously. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to spouse of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Rules and Regulations of the State of Georgia - [http://sos.georgia.gov/rules\\_regs.htm](http://sos.georgia.gov/rules_regs.htm)

## Hawaii

### Informed Consent

Health care provider must afford the patient the opportunity to decline testing, but specific written consent is not required - opt-out process (see State Policies Relating to HIV Testing, 2011). Verbal consent is acceptable at anonymous testing sites.

### Counseling

Pre-test counseling is not required for tests ordered by a health care provider. Post-test counseling must be offered in cases of reactive, indeterminate, or confirmed positive results.

### Provisos of Testing

- Anonymous - testing must be made available anonymous. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding disclosure were found.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV is explicitly included.

### Recommended Resources

Hawaii State Department of Health Administrative Rules - <http://www.hawaii.gov/health/about/rules/index.html>

## Idaho

### Informed Consent

No specific provisions regarding informed consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - availability of anonymous testing is not required.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding disclosure were found.

### Minor/Adolescent Testing

Persons 14 years of age or older may consent to testing for communicable diseases, HIV explicitly included.

### Recommended Resources

Idaho Statutes - <http://www3.state.id.us/idstat/TOC/idstTOC.html>

## Illinois

### Informed Consent

Informed consent may be through the opt-out process; included in general consent; and obtained verbally or in writing, as long as it is documented. This policy effect June 1, 2008.

### Counseling

Pre-test counseling must be offered; may be provided verbally, in writing, electronically, by video, or through other means, as long as patients are permitted to ask questions.

### Provisos of Testing

- Anonymous - physicians must inform patients of the availability of anonymous testing. Patients may request anonymous testing. All testing must be available anonymously.
- Rapid - a confirmatory test is required before notifying the patient of positive HIV test results.
- Routine - HIV testing should be made a routine part of general medical care, as recommended by the United States Centers for Disease Control and Prevention.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is not required.

### Minor/Adolescent Testing

Persons 12 years of age or older may consent to HIV testing. Physicians may, but are not required to, notify the parents of HIV test results.

### Recommended Resources

Illinois Administrative Code - <http://www.cyberdriveillinois.com/departments/index/home.html>

Illinois Department of Public Health Laws, Rules, and Proposed Rules -  
<http://www.idph.state.il.us/rulesregs/rules-indexhome.htm>

## Indiana

### Informed Consent

Specific informed consent required; may be oral or in writing.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - testing must be available anonymously.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Persons 14 years of age or older may consent to STD testing and treatment, HIV explicitly included.

### Recommended Resources

Indiana Administrative Code - State Department of Health - <http://www.in.gov/legislative/iac/title410.html>

## Iowa

### Informed Consent

HIV testing is implicitly included in a general consent for medical tests or procedures. If general medical consent is not used or is no longer in effect, specific informed consent may be oral or in writing.

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - anonymous testing is not available.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to HIV testing. Specific written informed consent is required. Health care provider or health facility is required to inform the legal guardian of an HIV positive result. Health facility must notify patient that legal guardian will be notified of an HIV positive result.

### Recommended Resources

Iowa Administrative Code - <http://legis.state.ia.us/IAC.html>

## Kansas

### Informed Consent

No specific provisions regarding informed consent were found.

### Counseling

Counseling must be offered.

### Provisos of Testing

- Anonymous - testing must be made available anonymously. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV not explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Kansas Administrative Regulations - <http://www.kslegislature.org/levsrv-kars/index.do>

## Kentucky

### Informed Consent

HIV testing is included in general medical consent (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - testing must be made available anonymous. Anonymous testing is available at designated anonymous testing sites.
- Rapid - a confirmatory test is required before notifying the patient of HIV test results.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV not explicitly included.

### Recommended Resources

Kentucky Legislature: Kentucky Revised Statutes - <http://www.lrc.state.ky.us/statrev/frontpg.htm>

Kentucky Administrative Regulations - <http://www.lrc.ky.gov/kar/frntpage.htm>

## Louisiana

### Informed Consent

Informed consent is required and through the opt-out process. HIV testing is included in general medical consent.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - testing must be made available anonymously.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - Diagnostic HIV testing may be offered to a person as part of a routine medical screening in health care settings, substance abuse treatment facilities, mental health treatment facilities, and correctional settings.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included.

### Recommended Resources

Louisiana State Legislature - <http://www.legis.state.la.us/>  
Louisiana Administrative Code - <http://state.la.us/osr/lac/books.htm>

## Maine

### Informed Consent

Informed consent required and through the opt-out process; may be oral or in writing.

### Counseling

- Post-test counseling is required for HIV positive results. Post-test counseling is required in cases of health care worker exposure.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included. Physicians may, but are not required to, inform the parents of the HIV test result.

### Recommended Resources

List of Titles, Maine Revised Statutes - <http://janus.state.me.us/legis/statutes/>  
Code of Main Rules - <http://www.maine.gov/sos/cec/rules/rules.html>

## Maryland

### Informed Consent

Informed consent required in a health care facility. Specific written informed consent required in a location other than a health care facility. (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

- Pre-test counseling may be written, oral, or by video. Post-test counseling is required for HIV positive results. Post-test counseling is required for HIV positive test results in cases of health care worker exposure.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - a confirmatory test must be offered.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included.

### Recommended Resources

Code of Maryland Regulations - <http://www.dsd.sate.md.us/comar/>

Maryland Department of Health and Hygiene - <http://www.dhmf.state.md.us/>

## Massachusetts

### Informed Consent

Specific informed consent required; must be in writing. (see State Policies Relating to HIV Testing, 2009).

### Counseling

- Counseling of all HIV/AIDS patients to modify high-risk behavior is required.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Massachusetts State Legislature - <http://www.mass.gov/legis/>

Code of Massachusetts Regulations - Reportable Diseases -

<http://www.mass.gov/Eeohhs2/docs/dph/regs/105cmr300.pdf>



## Michigan

### Informed Consent

Informed consent must be documented in the patient medical records; may be written or verbal and through the opt-out process. Informed consent may be incorporated into consent for general medical care, tests, and procedures.

### Counseling

Pre- and post-test counseling is required.

### Provisos of Testing

- Anonymous - anonymous testing must be made available.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to HIV testing and treatment. Physicians may, but are not required to, notify the parents of the HIV test results.

### Recommended Resources

Michigan Administrative Code - [http://michigan.gov/cis/0,1607,7-154-10576\\_35738\\_5698---,00.html](http://michigan.gov/cis/0,1607,7-154-10576_35738_5698---,00.html)

Michigan Legislature - <http://legislature.mi.gov>

## Minnesota

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding consent were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - routine testing is through the opt-out process.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included.

### Recommended Resources

Minnesota Statutes, Session Laws, and Rules - <http://www.leg.state.mn.us/leg/statutes.asp>

Minnesota Department of Health – HIV/AIDS Division - <http://www.health.state.mn.us/divs/idepc/diseases/HIV>

## Mississippi

### Informed Consent

Specific consent not required by hospitals, their staff, or physicians for the purpose of diagnosis, treatment, or protection of health and safety. Opt-out process is implied. Compatible with CDC Recommendations and Guidelines.

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - testing is not available.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to venereal disease testing and treatment, HIV not explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Mississippi Department of Health - <http://www.msdh.state.ms.us/>

Mississippi Legislature - <http://www.ls.state.ms.us/>

## Missouri

### Informed Consent

Informed consent is required; oral or written not specified.

### Counseling

Pre- and post-test counseling is required by health professionals other than physicians. The scope of pre- and post-test counseling shall be governed by the physician's judgment and shall be as comprehensive as consultation provided for other diagnostic tests.

### Provisos of Testing

- Anonymous - testing must be made available anonymous. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV not explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Missouri Revised Statutes - <http://www.moga.mo.gov/statutesearch/>

Missouri Code of State Regulations - <http://www.sos.mo.gov/adrules/csr/current/19csr/19csr.asp>

## Montana

### Informed Consent

Consent must be incorporated into the patient's general informed consent for medical care; may be oral or in writing with documentation of declination in the medical record.

### Counseling

Pre-test information to ensure the patient's knowledge and understanding that HIV diagnostic testing is planned and that testing is voluntary.

### Provisos of Testing

- Anonymous - no provisions regarding anonymous testing were found.
- Rapid - rapid testing shall be offered to women in labor if their status is unknown/undocumented.
- Routine - HIV screening is routine.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is encouraged but not required.

### Minor/Adolescent Testing

Emancipated minors may consent to STD testing and treatment, HIV explicitly included.

### Recommended Resources

Montana Department of Health and Human Services - <http://www.dphhs.state.mt.us/>  
Administrative Rules of Montana - <http://www.sos.mt.gov/>

## Nebraska

### Informed Consent

Specific informed consent required; must be in writing.

### Counseling

Post-test counseling is required with HIV positive test results in cases of occupational exposure.

### Provisos of Testing

- Anonymous - testing must be made available anonymous. Physicians must inform patients of availability of anonymous testing. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV not explicitly included.

### Recommended Resources

Laws of Nebraska: Nebraska Statutes and Constitution -  
[http://uniweb.legislature.ne.gov/Legal/Docs/view.php?page=index\\_statutes](http://uniweb.legislature.ne.gov/Legal/Docs/view.php?page=index_statutes)  
Nebraska Rules and Regulations - <http://www.sos.state.ne.us/business/regsearch/index.cgi>

## **Nevada**

### **Informed Consent**

No specific provisions regarding informed consent were found.

### **Counseling**

Post-test counseling is required with HIV positive test results.

### **Provisos of Testing**

- Anonymous - no provisions regarding anonymous testing were found.
- Rapid - rapid testing may be used on pregnant women. Rapid testing may be used on newborns.
- Routine - no specific provisions regarding routine testing were found.

### **Disclosure**

No specific provisions regarding the notification of partners or contacts were found.

### **Minor/Adolescent Testing**

Minors may consent to STD testing and treatment, HIV not explicitly included.

### **Recommended Resources**

Nevada Legislature - <http://www.leg.state.nv.us/>

Nevada State Health Division - <http://health2k.state.nv.us/>

## **New Hampshire**

### **Informed Consent**

Informed consent is required in accordance with CDC HIV testing consent recommendations (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### **Counseling**

Post-test counseling as appropriate.

### **Provisos of Testing**

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - a confirmatory test is required before notifying the patient of HIV test results.
- Routine - no specific provisions regarding routine testing were found.

### **Disclosure**

No specific provisions regarding the notification of partners and contact were found.

### **Minor/Adolescent Testing**

Persons 14 years of age or older may consent to STD testing, HIV not explicitly included.

### **Recommended Resources**

State of New Hampshire Revised Statutes Online -

<http://www.gencourt.state.nh.us/rsa/html/indexes/default.html>

New Hampshire Department of Health and Human Services -

[http://www.dhhs.state.nj.us/DHHS/DHHS\\_SITE/default.htm](http://www.dhhs.state.nj.us/DHHS/DHHS_SITE/default.htm)

## New Jersey

### Informed Consent

No specific provisions regarding informed consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners and contacts were found.

### Minor/Adolescent Testing

Minors 13 years or older may consent to HIV testing.

### Recommended Resources

New Jersey Legislature - <http://www.njleg.state.nj.us/>

New Jersey Department of Health and Senior Service – Division of HIV/AIDS Services - <http://www.state.nj.us/health/aids/aidsprv.htm>

## New Mexico

### Informed Consent

Informed consent is required; may be oral or in writing (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions); may be included in routine medical care.

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - HIV testing may be included as part of routine panel tests for pregnant women.

### Disclosure

No specific provisions regarding the notification of partners and contact were found.

### Minor/Adolescent Testing

Minors may consent to HIV testing.

### Recommended Resources

New Mexico Legislature - <http://legis.state.nm.us/lcs/default.asp>

New Mexico Department of Health - <http://www.health.nm.us/>

## New York

### Informed Consent

Informed consent required; must be in writing, except in cases of rapid testing. Written informed consent may be incorporated into the general medical consent. The general consent form shall have a clearly marked place adjacent to the signature where the subject shall be given an opportunity to specifically decline HIV testing in writing.

### Counseling

Pre-and (with negative results) post-test information is required; however, requirement may be fulfilled through written materials and an opportunity to ask questions. Compatible with CDC recommendations. In cases of HIV positive results, provider must give post-test counseling or a referral for counseling.

### Provisos of Testing

- Anonymous - physicians must inform patients of availability of anonymous testing. All testing must be available anonymously.
- Rapid - informed consent for a rapid test may be obtained orally and must be documented in the medical record. A confirmatory test is required before notifying the patient of HIV test results, except in perinatal testing.
- Routine - Practitioners are required to offer HIV testing to every individual ages 13-64 receiving health services.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to HIV testing. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

New York State Department of Health – HIV/AIDS - <http://www.health.state.ny.us/diseases/aids/index.htm>  
New York State Department of Health – Laws and Regulations - <http://www.health.state.ny.us/regulations>

## North Carolina

### Informed Consent

May use general informed consent; oral or written not specified (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

Post-test counseling with referrals for medical and psychosocial services for persons infected with HIV required; local health departments must offer free counseling.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - see "Prenatal and Neonatal Testing" in the individual state profile.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to partners of a possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing and treatment, HIV explicitly included.

### Recommended Resources

North Carolina Administrative Code - <http://reports.oah.state.nc.us/ncac.asp>  
North Carolina Department of Health and Human Services - <http://dhhs.state.nc.us/>

## North Dakota

### Informed Consent

Informed consent is required; oral or written not specified (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners and contacts were found.

### Minor/Adolescent Testing

Minors may consent to HIV testing.

### Recommended Resources

North Dakota Legislative Branch - <http://www.legis.nd.gov/>  
North Dakota Department of Health - <http://www.health.state.nd.us/>

## Ohio

### Informed Consent

HIV test may be given by or on the order of a health care provider who, in the exercise of the provider's professional judgment, determines the test to be necessary for providing diagnosis and treatment to the individual to be tested.

### Counseling

Post-test counseling in cases of HIV-positive results is required.

### Provisos of Testing

- Anonymous - patients may request anonymous testing. Anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - a policy to offer routine and voluntary testing may be adopted by a facility or physician.

### Disclosure

Notification to sexual partners of a possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV explicitly included.

### Recommended Resources

127th Ohio General Assembly - <http://legislature.state.oh.us/>  
Ohio Revised and Administrative Code - <http://codes.ohio.gov/>  
Ohio Department of Health - <http://www.odh.state.oh.us/>

## Oklahoma

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

Physicians must instruct in measures of preventing the spread of disease and of the necessity for treatment with HIV positive test results.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - rapid testing may be used on source patient in cases of occupational exposure of health care workers.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners and contacts were found.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV explicitly included. Physicians may, but are not required to, notify the parents of the HIV test result.

### Recommended Resources

Oklahoma Legislature - <http://www.lsb.state.ok.us/>

Oklahoma State Department of Health - <http://www.health.state.ok.us/>

## Oregon

### Informed Consent

Informed consent required; oral or written not specified (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - HIV test is included as part of routine panel of tests for pregnant women.

### Disclosure

Notification to sexual and needle-sharing partners of a possible exposure to HIV is not required.

### Minor/Adolescent Testing

Persons 15 years or younger may consent to HIV testing.

### Recommended Resources

Oregon Administrative Rules - <http://arcweb.sos.state.or.us/banners/rules.htm>

Oregon Department of Human Services – HIV/STD/TB Programs - <http://oregon.gov/DHS/ph/hst/index.shtml>



## Pennsylvania

### Informed Consent

Informed consent required; must be in writing.

### Counseling

Pre-test and post-test counseling is required.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - a confirmatory test is required before notifying the patient of HIV test results.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to services for reportable diseases, HIV explicitly included.

### Recommended Resources

Pennsylvania General Assembly - <http://www.legis.state.pa.us/>

Pennsylvania Department of Health - <http://www.dsf.health.state.pa.us/health/site/default.asp>

## Puerto Rico

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification to partners or contacts were found.

### Minor/Adolescent Testing

No specific provisions regarding minor or adolescent testing were found.

### Recommended Resources

Law Library of Congress: Puerto Rico - <http://loc.gov/law/guide/us-pr.html>

Puerto Rico Department of Health - <http://salud.gov.pr/>

## Rhode Island

### Informed Consent

Informed consent may be through the opt-out process and obtained verbally or in writing (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions); anonymous testing must be verbal.

### Counseling

- Pre-test information and opportunity for client-specific counseling tailored to the patient (to allow greater flexibility) must be offered with HIV testing and informed consent; information may be oral or written. HIV counseling means an interactive process of communication between a person and a health care provider or qualified professional HIV test counselor with an assessment of risk and the provision of counseling to assist the person with behavior changes to reduce risks. For positive results, post-test counseling must be given in person.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing (CTRS) sites.
- Rapid - rapid testing sites must seek a waiver from the department to provide confirmatory HIV testing from a lab other than the state lab, and shall forward all positive and negative confirmatory HIV test results to the department.
- Routine - a physician or health care provider attending to any person who may be at risk for HIV infection shall routinely offer the HIV test to those patients. HIV test may be included as part of routine panel of tests for pregnant women.

### Disclosure

Positive results must be given in person. Notification to partners of a possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to HIV testing and services.

### Recommended Resources

Rhode Island Rules and Regulations - <http://www.sec.state.ri.us/rules/>

Rhode Island Department of Health - <http://www.health.state.ri.us/>

Information for Providers: Laws, Rules, and Regulations - <http://www.health.ri.gov/hiv/laws.php>

## South Carolina

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Provisos of Testing

- Anonymous - anonymous testing is not available.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Person 16 years or older may consent to HIV testing.

### Recommended Resources

South Carolina Code of Laws - <http://www.scstatehouse.net/code/statmast.htm>

South Carolina Code of Regulations - <http://www.scstatehouse.net/coderegs/statmast.htm>

## South Dakota

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included.

### Recommended Resources

South Dakota Codified Laws - <http://legis.state.sd.us/statutes/index.aspx>

South Dakota Administrative Rules - <http://legis.state.sd.us/rules/index.aspx>

South Dakota Department of Health - <http://www.state.sd.us/doh>

## Tennessee

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - name-based reporting precludes anonymous testing.
- Rapid - Rapid testing may be used on pregnant women presenting to labor or delivery with undocumented HIV status.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV explicitly included.

### Recommended Resources

Tennessee Laws and Rules - <http://www.tennesseeanytime.org/laws/laws.html>

Tennessee Rules and Regulations - <http://state.tn.us/sos/rules/index.htm>

Tennessee State Department of Health - <http://www.state.tn.us/health/>

## Texas

### Informed Consent

Informed consent required; may be oral or in writing. HIV testing may be included in general medical consent.

### Counseling

Post-test counseling is required with HIV positive test results.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to partners of possible exposure to HIV is required.

### Minor/Adolescent Testing

Minors may consent for communicable diseases, HIV explicitly included.

### Recommended Resources

Texas Administrative Code - <http://www.sos.state.tx.us/tac/>

Texas Department of State Health Services - <http://www.tdh.state.tx.us/>

## Utah

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual and needle-sharing partners of possible exposure to HIV by health departments is required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included.

### Recommended Resources

Utah Code – Statutes and Constitution - <http://le.stat.ut.us/~code/code.htm>

Utah Department of Health - <http://health.utah.gov/>

## Vermont

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

No specific provisions regarding counseling were found.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Persons 12 years of age or older may consent to STD testing, HIV not explicitly included.

### Recommended Resources

The State of Vermont Legislature - <http://www.leg.state.vt.us>

Vermont Department of Health - <http://www.healthyvermonters.info/>

## Virginia

### Informed Consent

Prior to an HIV test, a medical care provider shall inform the patient that the test is planned, provide information about the test, and advise the patient that he has the right to decline the test. If a patient declines the test, the medical care provider shall note that fact in the patient's medical file. Opt-out process implied. Compatible with CDC Recommendations.

### Counseling

Persons who test positive shall be afforded individual face-to-face disclosure and the opportunity for post-test counseling. Appropriate counseling shall include, not not be limited to, the meaning of the test results, the need for additional testing, the etiology, prevention and effects of acquired immunodeficiency syndrome, the availability of appropriate health care, mental health care and social services, the need to notify any person who may have been exposed to the virus and the availability of assistance through the Department of Health in notifying such individuals.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

No specific provisions regarding the notification of partners or contacts were found.

### Minor/Adolescent Testing

Minors may consent to HIV testing. Physicians may, but are not required to, notify parents of the HIV test.

### Recommended Resources

The Code of Virginia - <http://leg1.state.va.us/000/src.htm>

Virginia Department of Health - <http://www.vdh.state.va.us/>

## Washington

### Informed Consent

Informed consent required and may be verbal or in written; may be obtained separately or as part of the consent for a battery of other routine tests; is through the opt-out process, an opportunity for questions and to decline testing must be offered.

### Counseling

Post-test counseling is required with HIV positive test results - Name and locating information of those testing HIV positive must be provided to the local health officer for follow-up post-test counseling.

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites. Any person authorized to order or prescribe an HIV test may offer anonymous testing without restriction.
- Rapid - rapid testing may be used on pregnant women presenting to labor or delivery (at a birth center). Persons may inform a tested individual of the unconfirmed results of a rapid HIV test provided the test result is interpreted as preliminarily positive, and the tested individual is informed that: (a) Further testing is necessary to confirm the reactive screening test result; (b) The meaning of reactive screening test result is explained in simple terms, avoiding technical jargon; (c) The importance of confirmatory testing is emphasized and a return visit for confirmatory test results is scheduled; and (d) The importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing is stressed.
- Routine - HIV testing may be included as part of a battery of other routine tests. HIV testing may be included as part of routine panel of tests for pregnant women.

### Disclosure

Assistance with partner notification (by local health officer) must be offered.

### Minor/Adolescent Testing

Persons 14 years of age or older may consent to STD testing, HIV explicitly included.

### Recommended Resources

Revised Code of Washington - <http://apps.leg.wa.gov/rcw/>  
Washington State Department of Health - <http://www.doh.wa.gov/>

## West Virginia

### Informed Consent

Informed consent required; may be oral or in writing (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions).

### Counseling

Post-test counseling is required; may be fulfilled with a brochure. Compatible with CDC recommendations and guidelines.

### Provisos of Testing

- Anonymous - all testing must be available anonymously.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of a possible exposure to HIV is not required.

### Minor/Adolescent Testing

Minors may consent to STD testing, HIV not explicitly included.

### Recommended Resources

West Virginia Legislature - <http://legis.state.wv.us/>  
West Virginia Department of Health and Human Resources - <http://www.wvdhhr.org>

## Wisconsin

### Informed Consent

Specific informed consent required; must be in writing (see State Policies Relating to HIV Testing, 2011, in the individual state profile, for exceptions):

- Must notify the person or the person's authorized representative that he or she may decline the HIV test and that the person will be subjected to an HIV test unless the test is declined.
- Must offer a brief oral or written explanation/description of HIV infection, HIV test results, requirements for reporting results, treatment options for a positive HIV test result, and AIDS service organizations and the services they provide to persons who have a positive HIV test result.
- Must notify that if the person or person's authorized representative declines to have an HIV test performed, the health care provider may not use the fact that the person declined an HIV test as a basis for denying services or treatment, other than an HIV test, to the person.
- Must provide an opportunity to ask questions and to decline the HIV test.
- Must verify understanding that an HIV test will be performed on the person and that the decision regarding whether to have an HIV test performed is not coerced or involuntary.

### Counseling

No specific provisions regarding counseling were found (counseling policies repealed April, 2010).

### Provisos of Testing

- Anonymous - anonymous testing is available at designated anonymous testing sites.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of possible exposure to HIV is encouraged but not required.

### Minor/Adolescent Testing

Persons 14 years of age or older or their authorized representatives may consent to HIV testing and treatment.

### Recommended Resources

The Updated Wisconsin Statutes and Annotations - <http://legis.state.wi.us/rsb/stats.html>  
Wisconsin Department of Health and Family Services - <http://www.dhfs.state.wi.us/>



## Wyoming

### Informed Consent

No specific provisions regarding consent were found.

### Counseling

Counseling may be offered with HIV positive test results.

### Provisos of Testing

- Anonymous - no specific provisions regarding anonymous testing were found.
- Rapid - no specific provisions regarding rapid testing were found.
- Routine - no specific provisions regarding routine testing were found.

### Disclosure

Notification to sexual partners of a possible exposure to HIV is required.

### Minor/Adolescent Testing

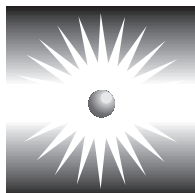
Persons 18 years or younger may consent to HIV testing.

### Recommended Resources

Wyoming Statutes - <http://legisweb.state.wy.us/titles/statutes.htm>

Wyoming Department of Health - <http://www.wdh.state.wy.us/main/index.asp>

# Quality Assurance Guidelines for Testing Using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test



**OraSure Technologies, Inc.**

*This document has been edited by OraSure Technologies from its original document "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test" authored by the CDC and other individuals found on Internet site:  
<http://wwwn.cdc.gov/cliac/pdf/Addenda/cia0903/C-GuidelinesOraQk.pdf>.*

*The edits contained in these Quality Assurance Guidelines reflect suggested changes for purposes of establishing a Quality Assurance Program with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. These changes have been provided as a guide in an effort to maintain the integrity and intent of the original document. These edits do not necessarily express the views of the original authors.*

## Introduction and Background

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<b>Purpose</b>	This document provides guidance on quality assurance (QA) practices for sites using or planning to use the OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test to detect antibodies to the human immunodeficiency virus (HIV).
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<b>Background</b>	The OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test is the first rapid HIV-1/2 point-of-care (i.e., testing and results are available in one visit) test approved by the U.S. Food and Drug Administration (FDA). It is also the first test for HIV-1/2 that the FDA has waived under the Clinical Laboratory Improvement Amendment regulations (CLIA). The OraQuick <i>ADVANCE</i> ® test uses oral fluid, whole blood obtained from puncture of a finger, whole blood obtained from a vein or plasma specimens. Results are available within 20 to 40 minutes. <sup>1</sup> Positive results with the OraQuick <i>ADVANCE</i> ® rapid test are preliminary, however, and must be followed up with an acceptable confirmatory test. Although the OraQuick <i>ADVANCE</i> ® test device is simple to use and can provide reliable results when the manufacturer's directions are followed, mistakes can occur at any point in the testing process. To reduce mistakes and to ensure that the FDA restrictions for sale of the test are followed (see Appendix A for information on the FDA sales restrictions), a site must have a QA program in place before offering OraQuick <i>ADVANCE</i> ® testing. The guidelines in this document outline the basic parts of a QA program.
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<b>How these guidelines were developed</b>	These guidelines were originally developed after many discussions on quality assurance for rapid HIV testing within the Centers for Disease Control and Prevention (CDC) and culminated from the discussions at a meeting of experts convened by the CDC at the end of January 2003. The original working group included individuals from Federal agencies— CDC, FDA, U.S. Department of Defense (DOD), and the Centers for Medicare & Medicaid Services (CMS)—as well as individuals outside the Federal government with expertise in rapid point-of-care testing, QA, HIV prevention programs, and private and public health laboratories. This revised guideline has been edited by OraSure Technologies in an effort to reflect the changes a QA program should assume when testing with the OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test. These revisions do not necessarily express the opinions of the original discussion panel.
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**How to use these guidelines**

This document outlines the basic processes and procedures that should be in place before a site offers rapid HIV testing. It describes steps that can be taken to identify and prevent errors in the testing process. Because the OraQuick *ADVANCE*® test will be used in many different settings, each site needs to decide how to fit the various QA elements into its own workflow and system of operation. For example, following these guidelines in a large clinic or hospital environment where on-site laboratory support is available may be quite different from using them in a small voluntary counseling and testing site or outreach setting with few staff and resources. These guidelines are intended to assist a range of providers in developing policies, processes and procedures to ensure high quality HIV testing services.

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**How this document is organized**

This document includes text and appendices that provide basic information that staff in sites offering OraQuick *ADVANCE*® testing should know. It includes information on:

- The basics of a QA program for testing using the OraQuick *ADVANCE*® test
  - An overview of government rules that apply to using this test
  - Examples of forms/checklists that can be used to keep track of QA outcomes
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# Basic Elements of a Quality Assurance Program

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**What is quality assurance?**

Quality assurance (QA) refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. Quality assurance activities should be in place during the entire testing process; this means from the time a person asks to be tested using the rapid test to providing the test result.

**How does quality assurance differ from quality control?**

As described above, QA is an overall program of activities throughout the entire testing process. Quality control (QC) is one part of the QA program. See page (8)11-12 for details on quality control testing for the OraQuick *ADVANCE*® test. Here are definitions for both terms<sup>2</sup>:

Term	Definition and activities performed
Quality assurance	Planned and organized activities to help ensure that certain requirements for quality will be met
Quality control	Operational techniques or tasks that are in place to find and correct problems that might occur

**Basic elements of a QA program for OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test**

Even though the OraQuick *ADVANCE*® test is simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering testing. These basic elements are the building blocks of a QA program and are listed below. More detail on these five elements is provided in this document.

- 1. Organization of the QA program
- 2. Testing personnel
- 3. Process control
  - a. Before testing
  - b. During testing
  - c. After testing
- 4. Documents and records
- 5. Troubleshooting

## Organization of the QA program

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### Establishing a QA program

Resources are needed to establish and maintain a QA program, no matter how simple. Someone must oversee the program and ensure the necessary staff and supplies are available. Each organization must:

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA program).
- Write procedures (step-by-step instructions) and make them available to all staff involved in testing (see the list of recommended procedures below).
- Verify the testing process (see below).
- Ensure staff know how to perform processes and procedures (see the section on personnel who conduct testing on page (8)6).
- Create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.
- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements. Each site offering testing must have a CLIA Certificate of Waiver if they are performing only the OraQuick *ADVANCE*® test or the OraQuick *ADVANCE*® test and other waived tests, or be included under an organization with a CLIA exception for limited public health or mobile testing. Each site must also meet Federal requirements for biohazard safety, as well as applicable State rules. See Appendix A for more information on regulatory requirements.

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### Verifying the testing process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. This verification should be completed before testing is offered. Verification includes ensuring that the staff have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g., make sure the test gives accurate results for a reference panel of non-reactive, weakly reactive and reactive specimens), and the logistics for providing confirmatory testing (if a person tests positive, he or she still has to have a test to confirm the finding) and biohazardous waste handling are in place.

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## Organization of the QA program (continued)

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### Providing written procedures

It is strongly recommended that step-by-step, written instructions be made available to all staff performing testing. This will help to ensure that personnel know how to perform specific tasks and testing success is not left to chance. Testing personnel must follow instructions provided by the manufacturer. Additional procedures, as listed below, should be provided along with the manufacturer's instructions. Text from the current OraQuick *ADVANCE*® package insert may be used for some of the items denoted by an asterisk (\*) in the list below. Written instructions should describe how to:

- Train new employees, assess their ability to do the testing and document training.
- Provide information to persons being tested before testing.\*
- Use gloves and other personal protective equipment when performing a fingerstick whole blood test. Oral Fluid is not considered potentially infectious unless it contains blood. Use of gloves for oral fluid testing is optional. (Refer to the CDC Guidelines for the Management of Occupational Exposures to HBV, HCV, HIV and Recommendations for Postexposure Prophylaxis).
- Maintain sufficient supplies and unexpired test and control kits, follow the manufacturer's instructions for storage, and check performance of new test kit lots and shipments with external controls as explained on page (8)11.
- Maintain and document the temperature of the room and refrigerator where the tests and controls are stored and testing is performed.
- Perform quality control testing and take action (e.g., contact the manufacturer) if controls don't work.
- Collect the OraQuick *ADVANCE*® specimen.\*
- Perform steps in the test procedure.\*
- Report results.
- Refer specimens or persons being tested for confirmatory testing and manage confirmatory test results.
- Record test and quality control results.
- Conduct external quality assessment (see description on page (8)11).
- Review records and store and destroy them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements).

## Testing Personnel

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### Overview

Having qualified, trained staff to perform and supervise OraQuick *ADVANCE*® testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Qualifications
  - Training
  - Competency assessment (i.e., how well they are doing their job)
- 

### Personnel qualifications

Since the OraQuick *ADVANCE*® test is waived under CLIA, there are no specific Federal requirements on who can perform the test. Each site should find out if there are State or other requirements for personnel that they must meet. Beyond any regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform the OraQuick *ADVANCE*® test. The following list of qualities resulted from practical considerations and expert opinion:

- *Sincerity and commitment* – A dedication to performing testing according to defined procedures.
  - *Literacy* – The ability to read instructions and record results is critical.
  - *Organizational skills* – The need for this quality will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
  - *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might come up.
  - *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.
- 

### Components of training

Training is crucial to ensuring quality testing.<sup>3</sup> Training is also required to be able to purchase the OraQuick *ADVANCE*® test kit (see Appendix A for details on the FDA sales restrictions). Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member; using training checklists is one way to handle this documentation (see Appendix B for an example of a training checklist). The key components to include in a training program are:

- How to perform the test, including procedures performed before, during and after testing.
  - How testing is integrated into the overall counseling and testing program.
  - The importance of QA and the elements of the site's QA program.
  - The use and importance of Universal (or Standard) Precautions/biohazard safety.
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## Testing Personnel (continued)

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<b>Training method</b>	<p>Experience with training to perform the OraQuick <i>ADVANCE</i>® test (CDC unpublished data) shows that a training method should optimally include the following activities:</p> <ul style="list-style-type: none"><li>• Read the instructions for performing the test.</li><li>• Watch someone perform the test or view a video of someone performing the test.</li><li>• Practice performing the test with a positive HIV-1, a positive HIV-2 and a negative control.</li><li>• Practice providing instruction to a colleague on how to obtain an oral fluid sample.*</li><li>• Practice performing the finger-stick collection procedure.*</li><li>• Review the procedures and forms on how to document testing.</li></ul>
<b>Competency assessment</b>	<p>Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or other interval as determined by the testing site. This assessment can be carried out in many ways, but regardless of the method, every task for which a staff member is responsible should be evaluated. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.</p>
<b>Assessing performance of tasks done before testing</b>	<p>To assess the task performance before testing, staff should be observed as they:</p> <ul style="list-style-type: none"><li>• Check and record the temperatures of the testing and storage areas.</li><li>• Set up the testing area, label the device and prepare control and test results log sheets.</li><li>• Run the external controls and record results.</li></ul>

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\*Refer to the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test package insert for complete instructions.

## Testing Personnel (continued)

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### Assessing performance of tasks during testing

To assess staff's ability to perform the test and interpret results:

- Observe the staff members instruction to a client for obtaining an oral fluid sample and placing the device into the testing vial.
- Observe the staff member performing the fingerstick, collecting the blood on a test loop and placing it into the testing vial.
- Observe how the test is performed on a client/patient. If such observation will interfere with actual client-provider interactions, observe test performance on a volunteer.
- Evaluate the use of Universal or Standard Precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal.
- Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include non-reactive, weakly reactive and reactive results. Control materials supplied by the manufacturer may be used as a source of specimens in the panel. In addition, specimens may be obtained from laboratories performing confirmatory testing or from other commercial sources.
- Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.

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### Assessing performance of tasks after testing

To assess task performance after testing:

- Review test records and quality control results documentation.
  - Observe oral reporting of results to a test subject (if trainee's responsibility).
  - Observe venous blood and/or oral fluid specimen collection and handling for confirmatory testing. If the frequency of OraQuick *ADVANCE*® reactive results is low, the trainee should be observed collecting blood and/or oral fluid from a staff volunteer and demonstrate how it is processed for confirmatory testing.
  - Verify that confidentiality is maintained.
-

# Process Control

**What is process control?** Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

**Steps in the testing process** Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in the table below. Detailed descriptions about each of the steps listed in this table are provided in the remainder of this document.



Before testing	During testing	After testing
<ul style="list-style-type: none"><li>• Check storage and room temperatures daily</li><li>• Check inventory and test kit lots as needed</li><li>• Receive request for testing</li><li>• Provide HIV/AIDS information</li><li>• Set up test area, label test device</li><li>• Perform external quality control according to the manufacturer’s and the site’s instructions</li></ul>	<ul style="list-style-type: none"><li>• Follow biohazard safety precautions</li><li>• Collect the oral fluid or fingerstick specimen</li><li>• Perform the test</li><li>• Interpret test results</li></ul>	<ul style="list-style-type: none"><li>• Clean up and dispose of biohazardous waste</li><li>• Report results to client</li><li>• Document results</li><li>• Collect, process and transport confirmatory test specimens</li><li>• Manage confirmatory test results</li><li>• Participate in external quality assessment (periodically)</li></ul>

## Before Testing

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### Overview

As shown in the table above, there are a number of steps that must be followed before testing the blood or oral fluid sample for HIV. These activities are in place to ensure that the conditions in which the tests are stored and performed are suitable, the test area and the test subject are prepared, and the test is working appropriately.

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### Temperature control: test kits and control kits

Test kits and controls must be stored in an environment within the temperature ranges specified by the manufacturer. Store test kits at 2° to 27° C (35° to 80° F). If test kits are refrigerated, the pouch containing the test device and developer solution must be brought to operating temperature (15° to 37° C or 59° to 99° F) before opening. Control kits must be refrigerated at 2° to 8° C (35° to 46° F). To ensure these temperature ranges are maintained, monitor and document temperatures of the storage area each day testing is performed. If the temperature falls outside of the specified range, take action as needed to adjust the temperature. To monitor the temperatures, place thermometers in the storage areas (e.g., in the refrigerator and on the shelf in the room where kits are stored). Check and record temperatures on a log sheet each day testing is performed. An example temperature log is provided in Appendix C.

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### Temperature control: testing area

The temperature in the area where the test will be performed must be within the range of 15° to 37° C (59° to 99°F). If the test must be performed at a temperature below 15°C/59°F or above 37°C/99°F, run external controls that have been stored within the proper temperature range to find out if the test can be performed at another temperature (see the section below on external controls). If testing is carried out in the field, monitor the temperature of the test and control kits in their portable storage containers and check the temperature where testing will be performed if it appears to be outside the specified range. If there are doubts about the testing area temperature or whether test kits have stayed within appropriate temperature range, run a positive and negative external control as described in the quality control section below.

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### Checking inventory and test kits

Procedures should be in place to ensure that an adequate supply of unexpired test kits, controls, and supplies is available. Test kits and controls have a defined shelf life. Use the oldest first. Never use test or control kits beyond their expiration dates. It is helpful to use a log sheet to document when test and control kits are received, their lot numbers and expiration dates. Also, once the control vials are opened, they are stable for 8 weeks. Therefore, record on the vial the date it is opened and discard unused opened controls after 8 weeks. As described in the package insert and in the section on quality control below run the positive HIV-1, positive HIV-2, and negative controls with new lots and new shipments of test kits before using them for testing, to verify that they work as expected.

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## Before Testing (continued)

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### Setting up the testing area and labeling the test

Before testing, the testing area should be prepared according to the specific site procedure, which should include directions for setting up the workspace listed in the test kit instructions, as well as instructions for how to label testing devices and complete report forms, including the method for identifying each person to be tested to ensure specimens are not mixed up during testing process. Labeling is especially important when more than one test is being performed at the same time. Label components of the test with the name or identifying number of the persons being tested before collecting the specimen. These components include the developer solution vial, test device, and documents for recording results. Using preprinted labels improve the efficiency of performing this task.

**Note:** *Do not place a label over the two holes on the back of the test device as this may cause an invalid result.*

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### Providing information to test subjects

OraSure Technologies, Inc., provides a “Subject Information” pamphlet that must be given to each person getting tested prior to performing the HIV rapid test. Each site may provide additional information. For further details, see the CDC website <http://www.cdc.gov/hiv/pubs/rt-counseling.htm>, the *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, MMWR Recommendations and Reports, RR-14, vol. 55, September 22, 2006<sup>4</sup> and applicable State or local rules.

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### Quality control

There are two types of quality control (QC) for the OraQuick *ADVANCE*® test. These are described in the table below.

Type of quality control	Description of activity
Internal controls	A control is built in to each testing device to verify that the specimen was adequate and the solution flowed through the device as intended.
External controls	Known reactive and non-reactive specimens (controls) are available from the manufacturer to sites purchasing the OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test. They are used to evaluate the accuracy of the test in detecting antibody to HIV and to check if the person conducting the test performs it correctly.

## Before Testing (continued)

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### **External quality control**

To verify that the test device is accurately detecting HIV-1 and/or HIV-2 antibodies, external positive and negative controls must be tested from time to time. The test kit manufacturer provides external controls in the form of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls. This control kit must be ordered separately from the test kit. It includes one vial each of an HIV antibody-negative (non-reactive), an HIV-1 antibody-positive (reactive for HIV-1 antibodies), and an HIV-2 antibody-positive (reactive for HIV-2 antibodies) human plasma control. How often controls are run to verify the accuracy of the test will depend on the number of tests carried out by the site, how often new test kit shipments or lot numbers are received by a site, changes in how the tests are stored and testing area temperature, and how often staff who conduct the testing change. An example of a log for control testing results is available in Appendix D.

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### **Run external controls according to the manufacturer's instructions**

The manufacturer has set guidelines for the minimum number of times to run the negative and positive controls. This is described in the test kit instructions, which specifies running controls under the following circumstances:

- By each new operator prior to performing testing on patients,
  - When opening a new test kit lot (a test kit lot is defined as the boxes of test devices that contain either 25 or 100 tests that have the same lot number labeled on the outside of the boxes),
  - Whenever a new shipment of test kits is received (even if it is the same kit lot number in current use),
  - If the temperature of the test storage area falls outside of 2°-27°C (35°-80°F),
  - If the temperature of the testing area falls outside of 15°-37°C (59°-99°F),
  - At periodic intervals as dictated by the user facility.
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## Before Testing (continued)

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### Frequency of running external controls on the basis of test volume

In addition to the specific circumstances listed in the manufacturer's instructions, testing sites should determine the optimal frequency for running controls on the basis of their test volume. When external controls provide incorrect results, none of the tests that were run since the last time control results were correct can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested (unless a confirmatory test was ordered). Sites testing large numbers of persons, and especially those that offer anonymous testing, should plan to run controls more often than facilities that conduct fewer tests. Each site needs to decide how often to run controls based on its own situation and testing practices. Instructions for some other waived tests recommend running external controls each time a new box of 25 tests is opened. Facilities that test 25 or more subjects a day should run controls every day. Low volume sites, such as those testing fewer than 25 subjects per month, should run external controls every two to four weeks at a minimum. Controls should be run more often if new lots or shipments are opened or if storage or testing temperatures fluctuate.

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## During Testing

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### Overview

This phase of the testing process involves running the test and interpreting the results. Activities during testing include observing specimen collection (oral fluid) or collecting the specimen (fingerstick whole blood), performing the test, interpreting the internal control and client/patient test results, and following biohazard safety guidelines when applicable.

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### Oral fluid collection

Follow the written procedure for an oral fluid specimen collection.

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### Fingerstick whole blood collection

Follow the written procedure for fingerstick specimen collection.

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## During Testing (continued)

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### Performing the test and interpreting results

Follow the manufacturer's instructions for performing the test and interpreting the results. Results can be one of the following:

- *Non-reactive* (negative)
- *Reactive* (preliminary positive)
- *Invalid* (the test is inconclusive and cannot be interpreted; see below for information on handling invalid results)

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### Evaluating internal control results

Each OraQuick *ADVANCE*® device includes a built-in (internal) control. When an appropriate line develops at the center of the "C" location on the device, the patient's specimen has been correctly loaded and traveled through the test strip, indicating a valid test. Additional information is provided in the test kit package insert. These controls are included in every device, and control results are evaluated with every test. If the internal control does not produce the expected result, the test result for the patient is not valid, cannot be reported, and the test must be repeated with a new specimen, developer solution vial, and test device. If a second invalid result occurs, external controls should be evaluated and OraSure Technologies contacted at 1-800-672-7873.

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### Running external controls to troubleshoot invalid results

CDC experience (unpublished data) has shown that external controls should be run to help find out if repeated invalid test results are due to the test device, test performance, or the patient specimen. If the same test kit lot yields repeated invalid results, the test kit may have been compromised. It is important to run the positive and negative controls whenever two consecutive invalid test results are obtained on a person being tested.

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### Biohazard safety/Universal (Standard) Precautions

All specimens and materials contacting specimens must be handled as if they are capable of transmitting an infectious organism. As described in Appendix A, each site must ensure that the Occupational Safety and Health Administration (OSHA) bloodborne pathogens are met; that is, persons doing the testing must know how to safely handle potentially infectious specimens. Also, according to Universal (Standard) Precautions, all human blood should be treated as if known to be infectious for HIV, hepatitis B virus, and other bloodborne pathogens. Sites must have available and follow procedures for biohazard safety including instructions for the use of gloves, hand washing, sharps, and biohazardous waste disposal, spill containment and disinfection. A different pair of gloves should be worn for collecting a specimen from each person being tested. Used gloves should be handled as biohazardous waste. For further details on these precautions, see the OraQuick *ADVANCE*® package insert, OSHA regulations and guidelines on Universal and Standard Precautions.<sup>1,6,7,8</sup>

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## After Testing

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### Overview

Quality assurance extends to those activities completed following the performance of the test. Each site should have established procedures for:

- Reporting and recording results,
  - Referring specimens (or test subjects, if specimens are not collected on-site) for confirmatory testing.
  - Managing confirmatory test results, and
  - Conducting external quality assessment.
- 

### Reporting results

Reporting procedures should describe how results are provided to the person being tested (verbal and/or written results) and how results are documented in the person's chart and in the test result logs. Some States have laws and regulations that include certain reporting criteria for HIV testing results. Check with your State agency for more information on these requirements. See Appendix E for an example of a test result log.

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### Referral for confirmatory testing

Whenever the OraQuick *ADVANCE*® test result is reactive (preliminary positive), a confirmatory test must be performed to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for referral of either test specimens or persons being tested for confirmatory testing when OraQuick *ADVANCE*® results are reactive. If specimens are collected on-site, the site must establish procedures describing how to collect, label, process, store and document specimen transfer; transport the confirmatory test specimens to the site(s) where they will be tested; and obtain the confirmatory results to give to the client/patients. It should be indicated on the specimen transfer sheet that the specimen is from an individual who had a reactive OraQuick *ADVANCE*® rapid test result. See Appendix F for an example of a specimen transfer sheet. Collecting confirmatory specimens on-site may improve follow-up, since some clients may not go elsewhere for testing or to obtain results. However, if the site is not able to collect confirmatory test specimens, a procedure must be in place for referring persons to another site to obtain this testing.

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## After Testing (continued)

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### Confirmatory testing protocols

For confirmatory testing, the current standard testing algorithm should be followed, with the following exceptions:

- All OraQuick *ADVANCE*® reactive (preliminary positive) results must be followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation.
- Confirmatory testing can be done on blood (plasma, serum or dried blood spots) or oral fluid specimens. Urine testing should not be performed due to its lower sensitivity (i.e., ability to detect positive results).
- With blood or oral fluid specimens, enzyme immunoassay (EIA) screening tests prior to the Western blot or IFA confirmatory test are optional. If an EIA is performed, even if it is non-reactive, the specimen must proceed to Western blot or IFA testing (reactive EIA specimens will automatically be tested by Western blot or IFA).\*

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### Follow up testing for negative confirmatory result

Most confirmatory test results will be positive; however, some may be negative or indeterminate. If the confirmatory test result is negative, specimen mix-up needs to be ruled out versus a false positive OraQuick *ADVANCE*® result. If the Western blot or IFA test is negative, it is recommended that:

- For blood specimens, a confirmatory test should be conducted as follow-up testing 4 weeks later with a new blood specimen.
- For oral fluid specimens, a repeat confirmatory test with a blood specimen should be conducted as follow-up testing 4 weeks later.\*

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### Follow up testing for indeterminate confirmatory results

Occasionally, confirmatory test results are indeterminate. If the Western blot or IFA is indeterminate, it is recommended that:

- For blood specimens, the person should be advised to return for repeat testing in one month. See *CDC's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>.
- For oral fluid specimens, the Western blot or IFA test should be repeated in one month using a blood specimen.

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\*MMWR Weekly Report, March 19, 2004/53 (10);221-222

## After Testing (continued)

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### Managing confirmatory results

OraQuick *ADVANCE*® testing sites that refer specimens for confirmatory testing should have established procedures describing how to:

- Match the client's/patient's confirmatory test results with their OraQuick *ADVANCE*® results to find potential discrepancies and to ensure that testing was performed according to the protocol described above,
  - Report the test result to the person being tested, and
  - Obtain any additional specimens needed to resolve potential specimen mix-up and for retesting, as needed.
- 

### Handling result discrepancies

Procedures should describe how to handle result discrepancies when the OraQuick *ADVANCE*® result was reactive and the confirmatory test negative or indeterminate. If the laboratory providing confirmatory testing performed an EIA test only and reported a non-reactive or negative result, the OraQuick *ADVANCE*® testing site should contact the confirmatory testing laboratory and request a Western blot test or IFA test. If the original specimen is not available, a new specimen will need to be collected from the person in question to be used for confirmatory testing.

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### External assessment

External assessment, or an evaluation of the testing process by a source outside the testing site, can look at how testing is being performed and whether it is being performed reliably. It can also help to identify existing or potential problems. Moreover, information gathered can provide an educational tool to improve performance. Some form of external assessment is highly recommended, but it is not required by Federal (CLIA) regulations since the test is waived and the test kit manufacturer does not specifically require it.

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### Methods for external assessment

Every reactive OraQuick *ADVANCE*® test is externally assessed by a second, confirmatory test. However, if there is a low prevalence of HIV infection in the population being tested, these assessments may be rare and will not provide an external check for the majority of the results, i.e., those that are non-reactive. Other ways to assess performance may be needed. Some external assessment mechanisms include:

- Comparing the OraQuick *ADVANCE*® reactive result with the confirmatory test results.
  - Arranging for someone outside the organization to observe testing.
  - Participating in a proficiency testing or external evaluation program (for more information on these programs, see Appendix G).
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## Documents and Records

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### Overview

One of the hallmarks of a QA program is comprehensive documentation. Sites using the OraQuick *ADVANCE*® test should have policies and procedures describing what QA records are required and how and when they are reviewed, stored and destroyed. Having a supervisor review records periodically is recommended. State regulations or other governmental or accrediting agencies may require facilities to have specific record retention policies. QA records include the following:

- Training documentation (Appendix B)
  - Temperature logs (Appendix C)
  - External control result logs (Appendix D)
  - Test result logs (Appendix E)
  - Specimen transfer logs (Appendix F)
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### Temperature logs

Temperature logs should include a daily record of the refrigerator temperature in which controls are stored, the temperature where test kits are stored and the temperature of the testing area. Thermometers should be placed in each location. Laboratory grade thermometers (can be purchased from medical or laboratory supply houses) are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.

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### External control result logs

External control records should include the date and time of control testing, lot number and expiration of the test kit, lot number and expiration date of the controls, control results, and corrective action taken if control results are unacceptable. Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.

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### Test result logs

Test result records should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid, blood), and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same kit lot number.

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## Troubleshooting

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<b>Overview</b>	Each site should have a method to detect and resolve problems that occur at any point in the testing process, especially those that may affect the accuracy of the test results. Significant problems should be immediately reported to the appropriate supervisory personnel.
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<b>Procedures</b>	<p>Procedures should be available to all testing personnel for the following:</p> <ul style="list-style-type: none"><li>• When to discontinue testing, e.g., when the external control results are unacceptable as described in the package insert.</li><li>• How to take corrective action, or an action taken in response to a problem, such as contacting the manufacturer when the external control results are unacceptable and following the advice provided.</li><li>• How to document problems and actions taken, such as a logbook where problems and corrective actions taken can be recorded.</li><li>• How to verify the corrective actions taken addressed the problem.</li></ul>
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## References

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## Appendix: Quality Assurance Guidelines for Testing Using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test

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### Overview

This appendix includes several items to facilitate conducting testing and performing quality assurance using OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The forms provided are examples and templates that can be adapted for local use, adding or deleting fields, as needed. The appendix includes the following:

- A. Government regulations
  - B. Example training checklist for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test
  - C. Example of a temperature log
  - D. Example log of quality control results
  - E. Example log of test results
  - F. Example specimen transfer log
  - G. External assessment: proficiency testing and other mailed evaluation programs
-

## Appendix A

### Government Regulations

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#### Food and Drug Administration (FDA) sales restrictions

To help ensure the quality of testing with the OraQuick *ADVANCE*® test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to the waived test kit. By purchasing the test, the customer agrees to follow these restrictions. The restrictions are outlined below (for the specific FDA language, refer to the OraQuick *ADVANCE*® package insert). The kit purchaser must:

- Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate – see below for details) and any State or other certification that is required.
  - Have an established quality assurance program.
  - Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
  - Provide information to persons being tested by giving each a copy of the manufacturer's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results.
  - Not use the kit to screen blood or tissue donors.
- 

#### Clinical Laboratory Improvement Amendment (CLIA) regulations

The OraQuick *ADVANCE*® test is a waived test under Federal regulations—the regulations for the Clinical Laboratory Improvement Amendments of 1988 (CLIA regulations). As a waived test, Federal requirements for the OraQuick *ADVANCE*® test are minimal. The CLIA requirements for sites wishing to offer testing using the OraQuick *ADVANCE*® test are listed below and can be found at [http://www.cms.gov/CLIA/09\\_Regulations\\_and\\_Federal\\_Register\\_Documents.asp#TopOfPage](http://www.cms.gov/CLIA/09_Regulations_and_Federal_Register_Documents.asp#TopOfPage). Each site must:

- Have a valid CLIA certificate of waiver, certificate of compliance or certificate of accreditation.
  - Follow the manufacturer's instructions for performing the test, and
  - Permit announced or unannounced inspections by representatives of the Centers for Medicare & Medicaid Services (CMS) under certain circumstances (see §493.35(d) in the regulations at the Web site listed above).
  - Perform only waived tests if holding a certificate of waiver.
-



## Government Regulations (continued)

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### How to obtain a CLIA certificate

All sites planning to offer only the OraQuick *ADVANCE*® test that are not already CLIA certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. To obtain a Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>. This form asks for information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing. The facility owner or laboratory director must sign the form. Mail the completed form to the State agency in which your site is located. To find your State agency contact, refer to the information provided at the following Internet address <http://www.cms.gov/CLIA/Downloads/CLIA.SA.pdf>. After the completed form is processed by the State agency, a fee of \$150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.

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### State regulations

In addition to CLIA, some States have specific regulatory requirements for HIV testing. Contact your State agency for information on State requirements. State agency contacts are list at <http://www.cms.gov/CLIA/Downloads/CLIA.SA.pdf>.

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## Government Regulations (continued)

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### Occupational safety and health regulations

Employers with employees who have an occupational exposure to blood or other potentially infectious materials must meet the U.S. Department of Labor Occupational Health and Safety Administrations (OSHA) standards for bloodborne pathogens. Individuals collecting blood specimens or performing the OraQuick *ADVANCE*® test have exposure to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering the OraQuick *ADVANCE*® test must meet OSHA standards that include, but are not limited to, the following requirements:

- Have a written Exposure Control Plan.
- Provide personal protective equipment, such as gloves.
- Make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure.
- Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident.
- Provide training for all employees with occupational exposure.
- Contain and dispose of biohazard waste following applicable regulations (includes blood and items contaminated with blood or other potentially infectious materials). Refer to State and local regulations regarding disposal of biohazardous materials.

NOTE: This is an overview of OSHA requirements and is not a complete list. For specific information, visit the OSHA Web site at <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>.

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## Appendix B

### Example Training Checklist for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test

Employee: Name

**Instructions:** Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable. See below as an example of a site conducting only oral fluid testing). The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	Date Observed	Date Performed	Trainee's Initial and Date	Trainer's Initial and Date
Read OraQuick <i>ADVANCE</i> ® procedure	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level workspace)				
Practice test with negative, positive HIV-1, and positive HIV-2 external controls				
Give person getting tested the "Subject Information" pamphlet				
Label test device components and appropriate paperwork				
Provide proper instruction and observe an oral fluid collection and insertion of test device into vial				
Collect fingerstick specimen, put loop into vial and mix correctly	N/A	N/A	N/A	N/A
Insert test device into vial	N/A	N/A	N/A	N/A
Time test, read result				
Dispose of lancet and/or other biohazardous waste materials appropriately				
Record results on report form and log sheet				
Record internal and external quality control (QC) results in QC log				
Evaluate a new OraQuick <i>ADVANCE</i> ® test kit lot number and record results in QC log				
Report test result to the person being tested (one negative and one preliminary positive)				
Refer person or collect specimen for confirmatory testing				
Send confirmatory test specimen to referral laboratory and document submission				
Receive referral laboratory results and record results				
Explain what to do if QC results show a problem				

## Appendix C

### Example Temperature Log

Thermometer location: \_\_\_\_\_

Acceptable temperature range\*: \_\_\_\_\_

Month/Year: \_\_\_\_\_

Day	Temperature	Initials	Day	Temperature	Initials
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

\*The acceptable range for test kit storage is 2° to 27°C or 35° to 80°F; the acceptable range for control kit storage is 2° to 8°C or 35° to 46°F; the acceptable range for the testing area is 15° to 37°C or 59° to 99°F.

**NOTE:** Periodically (e.g., every six months) check thermometer performance and document.

#### Corrective Action

Date	Action Taken	Initials

Reviewed by and date: \_\_\_\_\_

# **Appendix D** **Example Log of Control Results**

Date	Time	Test Kit Lot #	Test Kit Exp. Date.*	New Lot #, Shipment?	Control Kit Lot #	Control Kit. Exp. Date	Date Controls Opened	Negative Control Result	HIV-1 Positive Control Result	HIV-2 Positive Control Result	Results Acceptable	Performed by	Reviewed by and Date

\*Exp. = Expiration

## **Corrective Action** (use reverse side, if needed)

Date	Action Taken	Initials	Reviewed by and date

## Appendix E

### Example Log of Test Results

Test Subject ID*	Date and Time Specimen Collected	Kit Lot #	Test Kit Exp. Date.	Actual Test Incubation Time	Test Result N=non-reactive R=reactive I=invalid	Tester	Result and Time Reported to Subject	Confirmatory Testing					Reviewed by and Date
								Tracking #	Specimen Type (Blood or Oral Fluid)	Result	Date Result Received	Date Result Given to Test Subject	

\*ID = Identification

## Appendix F

### Example Specimen Transfer Log

[Put Referring Facility Name,  
Address and Phone Number Here]

Date: \_\_\_\_\_

Referral Laboratory: \_\_\_\_\_

Specimen Tracking Number	Test Subject ID*	OraQuick Test Result	Date Specimen Collected	Time Specimen Collected	Collected by	Referral Lab Req <sup>†</sup> Completed ( )	Date Conf Result Received	Confirm Test Result

\*ID = Identification

<sup>†</sup>Lab Req = Laboratory Requisition

(NOTE: If you use more than one referral laboratory, add a column to record each one.)

## Appendix G

### External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

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#### Background and overview

Some States may require participation in a State or Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing program, even though this program is not required by CLIA for waived tests. Participating in proficiency testing or an external evaluation program is a relatively easy way to obtain an external assessment of the quality of waived testing. There are several programs in which a site may choose to enroll. Test samples will be received by mail on a periodic basis, usually two to three times per year. These samples include a combination of several (typically five) HIV antibody positive and negative specimens with results known to the program provider, but not to the participants. The participants test the samples as if they were client/patient specimens and send results back to the program provider.

---

#### Evaluation reports

In proficiency testing programs, the results from the individual participant sites are compared to the expected values. Each site receives a graded individualized report and summary report showing their performance and the performance of all the participants. In some evaluation programs, individual participant results are not graded; instead a summary report is provided with a compilation of results from all participants and a commentary on overall performance.

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## **Support Documents and Forms**

Checklist for Conducting Rapid HIV Tests .....	2
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Client Test Result Log .....	9
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Investigational and Remedial Action on Unacceptable Proficiency Testing .....	24
Clinic Communication and Complaint Log .....	25
Skills Performance Criteria .....	27

# Checklist for Conducting Rapid HIV Tests

---

## General Test Preparation

- ☐ Conditions for testing verified (temperature and lighting)
- ☐ Expiration date verified on Pouch
- ☐ Clean, disposable absorbent workspace cover
- ☐ Manufacturer's Stand used
- ☐ Stand is on flat level surface
- ☐ Test Device left in pouch until needed (not contaminated)
- ☐ Absorbent Packet included in Pouch
- ☐ Vial slid into Stand
- ☐ Vial is completely seated in Stand
- ☐ Two holes in back of Test Device not covered
- ☐ Subject Information Pamphlet provided to client

## Sample Collection and Test Procedures - Oral Fluid Collection

- ☐ Client removed device from Pouch
- ☐ Instructed client on proper oral fluid collection procedure
- ☐ Observed oral fluid collection
- ☐ Test device was inserted device as instructed into Developer Vial
- ☐ Pad on the Test Device touched the bottom of the vial
- ☐ Results Window faced forward
- ☐ Timer used
- ☐ Results read between 20 and 40 minutes after Test Device inserted into the vial
- ☐ Test Device read while in Developer Solution Vial
- ☐ Test results properly recorded

## Checklist for Conducting Rapid HIV Tests

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### Sample Collection and Test Procedures - Fingerstick Whole Blood Collection

- ☐ Disposable gloves worn
- ☐ Client finger cleaned with antiseptic wipe
- ☐ Finger allowed to dry thoroughly
- ☐ Second drop of blood collected
- ☐ Loop was completely filled with blood
- ☐ Loop stirred into Developer Solution
- ☐ Solution turned pink
- ☐ Pad on the Test Device touched the bottom of the vial
- ☐ Results Window faced forward
- ☐ Timer used
- ☐ Results read between 20 and 40 minutes after Test Device inserted into the vial
- ☐ Test Device read while in Developer Solution Vial
- ☐ Test results properly recorded

### Quality Control (To be conducted as per manufacturer's guidelines)

- ☐ Kit Controls run; Date and Time\_\_\_\_\_
- ☐ Kit Controls verify Control Test Results match the expected results
- ☐ Good lighting used with Controls
- ☐ Test viewed good lighting conditions
- ☐ Clinic room temperature checked and recorded

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## Consent to Test for HIV – Anonymous

---

Anonymous consent form to be completed by COUNSELOR to verify verbal consent given by client. No client identifying information should appear on this form.

Cnslr  
initials

\_\_\_\_\_ Client has been informed of the differences between anonymous and confidential HIV testing. Client understands that reactive HIV test results will be forwarded using a non-names code to the \_\_\_\_\_ Department of Health for record-keeping purposes.

\_\_\_\_\_ Client has been informed about the limitations and implications of HIV tests. Client understands that HIV tests' accuracy and reliability are not 100% certain.

Cnslr  
initials

### Rapid Testing Only

\_\_\_\_\_ Client has been informed that s/he will receive his/her initial HIV test result before leaving today. Client understands that a negative test result is final and does not require confirmation.

\_\_\_\_\_ Client has been informed that a reactive rapid HIV test result must be confirmed by a laboratory based test. Client consents to give a blood or oral fluid sample for this confirmatory test if his/her initial test result is reactive.

---

**Counselor:** By my signature below, I affirm that I have provided information to the client concerning the benefits and risks of HIV testing, and that s/he has had a chance to ask questions which were answered to his/her satisfaction. I affirm that the client has given verbal consent to each of the points initialed above, and does consent to submit a blood or oral fluid sample to be tested for HIV.

Date

\_\_\_\_\_

Counselor Signature

\_\_\_\_\_

Counselor Printed Name

\_\_\_\_\_

## Consentimiento para Hacer la Prueba de VIH – Anónimo

---

Forma de consentimiento será completado por un/a CONSEJERO/A para verificar que consentimiento verbal fue proveido por el cliente. Ninguna información que identifique el cliente debería de aparecer en esta forma.

Iniciales del  
consejero/a

\_\_\_\_\_ El cliente ha sido informado acerca de las diferencias entre las pruebas anónima y confidencial del VIH. El cliente comprende que los resultados reactivos de la prueba de VIH serán mandado utilizando un código sin nombre al Departamento de Salud de \_\_\_\_\_ para recordar datos.

\_\_\_\_\_ El cliente has sido informado sobre las limitaciones e implicaciones de las pruebas de VIH. El cliente comprende que la exactitud y veracidad de las pruebas de VIH no son 100% seguro.

---

Iniciales del  
consejero/a

### La Prueba Rápida Solamente

\_\_\_\_\_ El cliente ha sido informado que hoy, antes de salir, recibirá el resultado inicial de su prueba de VIH. El cliente comprende que un resultado negativo es final y no requiere confirmación.

\_\_\_\_\_ El cliente ha sido informado que un resultado positivo de la prueba rápida de VIH tiene que ser confirmado por una prueba del laboratorio. Consiente dar una muestra de sangre o fluido oral para esta prueba confirmatoria si su prueba inicial sale positiva.

---

**Consejero/a:** Con mi firma que sigue, afirmo que he proveido información al cliente que explica los beneficios y riesgos de las pruebas de VIH, y el cliente tuvo la oportunidad de hacer preguntas que fueron contestadas de manera satisfactoria. Afirmo que el cliente ha dado consentimiento verbal para cada punto inicializado arriba, y consiente someter una muestra de sangre o fluido oral para recibir la prueba de VIH.

Fecha

Firma del Consejero/a

\_\_\_\_\_

\_\_\_\_\_

Nombre en Letras Molde del Consejero/a

\_\_\_\_\_

## Consent to Test for HIV – Confidential

---

Client  
initials

\_\_\_\_\_ I have been informed of the differences between anonymous and confidential HIV testing. I understand that reactive HIV test results will be forwarded using a non-names code to the \_\_\_\_\_ Department of Health for record-keeping purposes.

\_\_\_\_\_ I have been informed about the limitations and implications of HIV tests. I understand that HIV tests' accuracy and reliability are not 100% certain.

---

Client  
initials

### Rapid Testing Only

\_\_\_\_\_ I have been informed that I will receive my initial HIV test result before I leave today. I understand that a negative test result is final and does not require confirmation.

\_\_\_\_\_ I have been informed that a reactive rapid HIV test result must be confirmed by a laboratory based test. I consent to give a blood or oral fluid sample for this confirmatory test if my initial test result is reactive.

---

By my signature below, I acknowledge that I have been given information concerning the benefits and risks of HIV testing, and have had a chance to ask questions which were answered to my satisfaction. I consent to submit a blood or oral fluid sample to be tested for HIV.

\_\_\_\_\_ Date

\_\_\_\_\_ Signature

\_\_\_\_\_ Last 4 digits SS #

\_\_\_\_\_ Printed Name

---

Client  
initials

### Contact Information

\_\_\_\_\_ In the event that I miss my follow-up appointment, I consent to be contacted by \_\_\_\_\_ to reschedule my missed appointment.  
(agency representative)

_____ Address		
_____ City	_____ State	_____ Zip Code
_____ Home phone	_____ Alternate phone	
Additional contact instructions: _____		

## Consentimiento para Hacer la Prueba de VIH – Confidencial

Iniciales

del Cliente

- \_\_\_\_\_ He sido informado sobre las diferencias entre las pruebas anónima y confidencial de VIH. Comprendo que los resultados de la prueba reactiva de VIH serán reportado al Departamento de Salud de \_\_\_\_\_ para archivar los datos utilizando un código sin nombre.
- \_\_\_\_\_ He sido informado sobre las limitaciones e implicaciones de las pruebas de VIH. Comprendo que la exactitud y veracidad de las pruebas de VIH no son 100% seguro.

Iniciales

del Cliente

### La Prueba Rápida Solamente

- \_\_\_\_\_ He sido informado que hoy recibiré el resultado inicial de mi prueba de VIH antes de salir. Comprendo que un resultado negativo es final y no requiere confirmación.
- \_\_\_\_\_ He sido informado que un resultado positivo de la prueba rápida de VIH tiene que ser confirmado por una prueba del laboratorio. Consiento dar una muestra de sangre o fluido oral para esta prueba confirmatoria si mi prueba inicial sale positiva.

Con mi firma que sigue, confirmo que he recibido información que explica los beneficios y riesgos de las pruebas de VIH, y tuve la oportunidad de hacer preguntas que fueron contestadas de manera satisfactoria. Consiento someter una muestra de sangre o fluido oral para recibir la prueba de VIH.

Fecha

Firma

Nombre en Letras de Molde

Iniciales

del Cliente

### Información de Contacto

- \_\_\_\_\_ Si falto a mi cita de seguimiento, consiento ser contactado por \_\_\_\_\_ para hacer una cita nueva.  
(representante de agencia)

Dirección		
Ciudad	Estado	Código Postal
Teléfono de casa	Teléfono alternativo	
Instrucciones adicionales para contactarme		



## Preliminary HIV Positive Enhanced Risk Assessment Tool

---

**In the last 3 months:**

- |  |                                       |                                       |
|--|---------------------------------------|---------------------------------------|
| Have you had unprotected vaginal sex?  | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have you had unprotected oral sex?   | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have you had unprotected anal sex?   | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have you had more than one partner?  | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have you had a sexually transmitted disease?   | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| <b>IF YES,</b>   | <input type="checkbox"/> Diagnosed(?) | <input type="checkbox"/> Suspected(?) |
| Have you had unplanned sex because you were under the influence of drugs and/or alcohol? | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have you shared needles, syringes or piercing needles with another person?               | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Do you think any of your partners have had another sexual partner?                       | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Do you think any of your partners have used injectable drugs?                            | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |
| Have any of your sex or needle-sharing partners had a positive test for HIV/AIDS?        | <input type="checkbox"/> YES          | <input type="checkbox"/> NO           |

Clinic Name/Site Location: \_\_\_\_\_

Name/ID Number: \_\_\_\_\_ Date: \_\_\_\_\_

Counselor/Tester: \_\_\_\_\_ Date: \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

# OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

## Client Test Result Log

Clinic Name: \_\_\_\_\_

Testing Location: \_\_\_\_\_

Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Test Result	Result & Type of Confirmatory Blood or Oral Fluid	Date Client Received Test Result	How Result Received: by Confirmed Phone (PH) or Result in Person (IP)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	<div style="display: flex; justify-content: space-around;"> <div> <p>Non-Reactive</p> </div> <div> <p>Reactive</p> </div> <div> <p>Invalid</p> </div> </div> <p>(circle one)</p>		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)

# OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

## Client Test Result Log

Clinic Name: \_\_\_\_\_

Testing Location: \_\_\_\_\_

Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Result	Result & Type of Confirmatory Blood or Oral Fluid	Date Client Received Test Confirmed Result	How Result Received: by Phone (PH) or Result in Person (IP)
Virginia Hall	#938-LB	09/05/03	First <input checked="" type="checkbox"/> Second <input type="checkbox"/>	#1234567	8:45 a.m. (circle one)	72.6 °F (circle one)	9:08 a.m. (circle one)	72.6 °F (circle one)	 Non- Reactive      Reactive (circle one)	9/5/03	<input checked="" type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
#12345678						N/A							
Mark Dewitt	#938-LB	09/05/03	First <input checked="" type="checkbox"/> Second <input type="checkbox"/>	#1234567	9:42 a.m. (circle one)	72.4 °F (circle one)	10:10 a.m. (circle one)	72.0 °F (circle one)	 Non- Reactive      Reactive (circle one)	Preliminary Positive 9/5/03	<input type="checkbox"/> Blood <input checked="" type="checkbox"/> Oral Fluid <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative	9/16/03	PH IP (circle one)
#12345679													
Theresa Howard	#938-LB	09/05/03	First <input checked="" type="checkbox"/> Second <input type="checkbox"/>	#1234567	11:55 a.m. (circle one)	72.0 °F (circle one)	12:17 p.m. (circle one)	72.0 °F (circle one)	 Non- Reactive      Reactive (circle one)	Invalid N/A	<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
#12345680													
Theresa Howard	#938-LB	09/05/03	First <input type="checkbox"/> Second <input checked="" type="checkbox"/>	#1234567	12:30 a.m. (circle one)	72.1 °F (circle one)	12:50 p.m. (circle one)	72.2 °F (circle one)	 Non- Reactive      Reactive (circle one)	9/5/03	<input checked="" type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative	N/A	PH IP (circle one)
#12345680						Repeat Test							
			First <input type="checkbox"/> Second <input type="checkbox"/>		a.m. (circle one)	°F (circle one)	a.m. (circle one)	°F (circle one)	 Non- Reactive      Reactive (circle one)		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			First <input type="checkbox"/> Second <input type="checkbox"/>		a.m. (circle one)	°F (circle one)	a.m. (circle one)	°F (circle one)	 Non- Reactive      Reactive (circle one)		<input type="checkbox"/> Blood <input type="checkbox"/> Oral Fluid <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)

## OraQuick *ADVANCE*® Product Information Training

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Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

Select the best response for statements 1 through 6:

1. **The complete storage temperature range of the OraQuick *ADVANCE*® Test Kit is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–27°C; 35–80°F
  - (c) comfortable room temperature - 15°–27°C; 59°–80°F
2. **The complete storage temperature range of the OraQuick *ADVANCE*® Kit Controls is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–27°C; 35–80°F
  - (c) comfortable room temperature - 15°–27°C; 59°–80°F
3. **The acceptable temperature range for performing OraQuick *ADVANCE*® Test is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–37°C; 35–99°F
  - (c) comfortable room temperature - 15°–37°C; 59°–99°F
4. **According to the manufacturer's instructions, the acceptable time to read the OraQuick *ADVANCE*® Test Device result is**
  - (a) 10 to 30 minutes
  - (b) 20 to 40 minutes
  - (c) 20 to 80 minutes
  - (d) 10 to 60 minutes
5. **The three possible OraQuick *ADVANCE*® Test Device result outcomes are**
  - (a) reactive, non-reactive, borderline
  - (b) reactive, non-reactive, inconclusive
  - (c) reactive, non-reactive, weakly reactive
  - (d) reactive, non-reactive, invalid
6. **The blood-filled Specimen Collection Loop**
  - (a) should be rapidly dipped in the Developer Solution Vial and discarded
  - (b) should be stirred in the Developer Solution Vial and then discarded
  - (c) can be left in the Developer Solution Vial for up to 10 minutes and discarded
  - (d) should be stirred in the Developer Solution Vial and then saved until the test is complete

Select True or False for Statements 7 – 16:

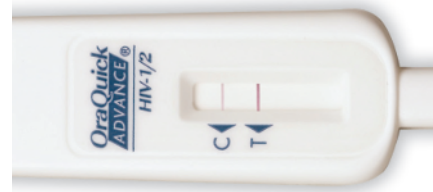
7. When conducting an OraQuick *ADVANCE*® Test Control, if the positive and/or negative control does not give the correct result(s), clients can still be tested with the OraQuick *ADVANCE*® Kits.
- True                      False
8. If the absorbent packet is not present when opening the OraQuick *ADVANCE*® pouch, the pouch contents should be allowed to remain open for 5 – 10 minutes before using.
- True                      False
9. The 2 holes in the back of the OraQuick *ADVANCE*® Test Device must be covered after placing the device into the Developer Solution Vial.
- True                      False
10. The built-in procedural control in the OraQuick *ADVANCE*® Test Device is intended to confirm that that the patient sample has moved past the Test (T) area.
- True                      False
11. The Developer Solution Vial must turn pink after adding the fingerstick whole blood sample.
- True                      False
12. The OraQuick *ADVANCE*® Test Device should not be removed from the Developer Solution Vial before reading the Test result.
- True                      False
13. The first drop of blood from a fingerstick can be use to perform the OraQuick *ADVANCE*® test.
- True                      False
14. An OraQuick *ADVANCE*® reactive test result is interpreted as a confirmed positive test for the presence of HIV-1 and/or HIV-2 antibodies.
- True                      False
15. OraQuick *ADVANCE*® is currently approved for use in the U.S. with fingerstick whole blood specimens only.
- True                      False
16. In the U.S., OraQuick *ADVANCE*® is currently approved for use to detect HIV-1 and/or HIV-2.
- True                      False

# OraQuick ADVANCE® HIV-1/2 Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_  
Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_



Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_



Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_ Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)

# OraQuick ADVANCE® HIV-1/2 Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

1



Result: \_\_\_\_\_

2



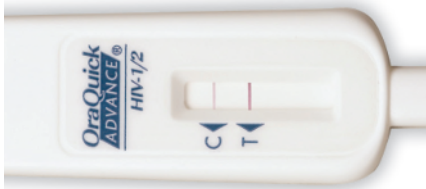
Result: \_\_\_\_\_

3



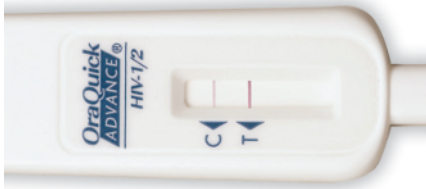
Result: \_\_\_\_\_

4



Result: \_\_\_\_\_

5



Result: \_\_\_\_\_

6



Result: \_\_\_\_\_

7



Result: \_\_\_\_\_

8



Result: \_\_\_\_\_

9



Result: \_\_\_\_\_

10



Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)

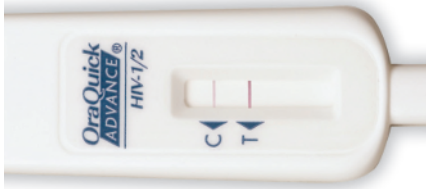
# OraQuick ADVANCE® HIV-1/2 Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

1



Result: \_\_\_\_\_

2



Result: \_\_\_\_\_

3



Result: \_\_\_\_\_

4



Result: \_\_\_\_\_

5



Result: \_\_\_\_\_

6



Result: \_\_\_\_\_

7



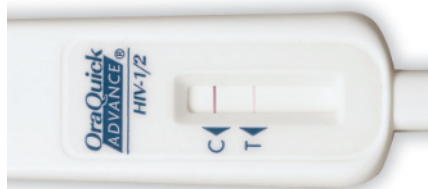
Result: \_\_\_\_\_

8



Result: \_\_\_\_\_

9



Result: \_\_\_\_\_

10



Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)



# OraQuick ADVANCE® HIV-1/2 Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_  
Score: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)

# OraQuick ADVANCE® HIV-1/2 Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

1



Result: \_\_\_\_\_

2



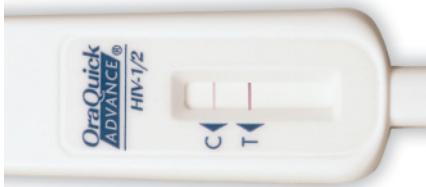
Result: \_\_\_\_\_

3



Result: \_\_\_\_\_

4



Result: \_\_\_\_\_

5



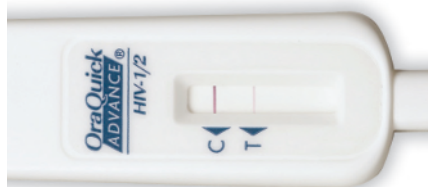
Result: \_\_\_\_\_

6



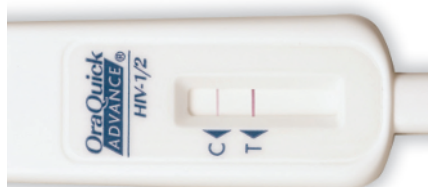
Result: \_\_\_\_\_

7



Result: \_\_\_\_\_

8



Result: \_\_\_\_\_

9



Result: \_\_\_\_\_

10



Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)

# OraQuick *ADVANCE*® Training Answer Key

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## OraQuick *ADVANCE*® Product Information Training

- 1) **B.** Storage conditions for the OraQuick *ADVANCE*® Test Kits is **2–27°C; 35–80°F**.
- 2) **A.** Storage conditions for the OraQuick *ADVANCE*® Kit Controls is **2–8°C; 35–46°F**.
- 3) **C.** Acceptable temperature range for performing the OraQuick *ADVANCE*® Test Device is a comfortable room temperature of **15°–37°C; 59°–99°F**.
- 4) **B.** Acceptable times to read the OraQuick *ADVANCE*® Test Device is **20 minutes to 40 minutes**. DO NOT attempt to read the test result after the 40 minute test development.
- 5) **D.** The three possible OraQuick *ADVANCE*® Test result outcomes is **(R) Reactive, (NR) Non-Reactive and (INV) Invalid**. An Invalid test result cannot be interpreted and is an indication that there was a problem running the test, either related to the specimen or the Device. A repeat test should be performed with a new Pouch and new sample.
- 6) **B.** The blood-filled Specimen Collection Loop should be gently **stirred in the Developer Solution Vial and then immediately discarded** in a bio-hazard waste container.
- 7) **False.** When conducting an OraQuick *ADVANCE*® Kit Control, should the test results not perform as expected, NO client samples should be tested until a proper investigation and evaluation has been conducted. Improper storage conditions of either the Kit Controls and/or the Test Device may influence the test's performance. Temperatures for testing location may be outside the recommended acceptable testing range. Similarly, user technique for QA Testing, may also have influenced test results.
- 8) **False.** An absorbent packet is included in each Device Pouch to ensure that moisture levels are maintained and do not compromise the Test Device performance. The absence of an absorbent packet means that the Test Device may have been compromised during storage. Immediately discard package, device and developer vial and open a new pouch to proceed.
- 9) **False.** The two holes at the back of the OraQuick *ADVANCE*® Test Device are part of the design of the lateral flow system. Blocking these holes with labels and or other materials will interfere with the test development.
- 10) **True.** The built-in procedural control on the OraQuick *ADVANCE*® Test Device is designed to verify that the chemistry of the test has flowed past the "T" or Test Line of the Device and that a correct human sample was added to the Developer Vial Solution.
- 11) **True.** If the blood-filled loop has been properly introduced to the Developer Solution Vial, the solution will turn a shade of pink indicating sample has been mixed.
- 12) **True.** The OraQuick *ADVANCE*® Test Device **should not** be removed from the Developer Solution Vial until the test result has been read, interpreted and documented.
- 13) **False.** The first droplet of blood should be wiped away from the finger. Typically, the first droplet will contain tissue sample as well as blood. This may interfere with the test performance. Apply the loop to the second droplet for a clean sample.
- 14) **False.** An OraQuick *ADVANCE*® Reactive test results is reported as a **PRELIMINARY POSITIVE**. OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a qualitative immunoassay test only. A licensed confirmatory test such as a Western Blot must be performed.
- 15) **False.** OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is approved for use in the U.S. for oral fluid, fingerstick and venipuncture whole blood and plasma specimens.
- 16) **True.** In the U.S., OraQuick *ADVANCE*® is approved to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and/or Human Immunodeficiency Virus Type 2 (HIV-2).

# OraQuick *ADVANCE*® Training Answer Key

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## OraQuick *ADVANCE*® Rapid Test Result Panel Training - A

- 1) **NR.** Test line appears only in the “C” designated area, indicating no detection of HIV-1 and/or HIV-2 antibodies are present at the time the test was conducted.
- 2) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HIV-1 and/or HIV-2 antibodies have been detected. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HIV virus.
- 3) **INV.** Test line appears below the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 4) **INV.** Test line appears only in the “T” designated area. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 5) **INV.** No test lines appear in the “T” or “C” designated areas. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 6) **INV.** Test line appears above the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 7) **INV.** No test lines appear in the “T” or “C” designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 8) **INV.** Test lines appear outside the “T” and “C” designated areas. While on appearance, it would seem that a PRELIMINARY POSITIVE could be interpreted, the registration of the test lines are not in alignment with the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 9) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 10) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.

## OraQuick *ADVANCE*® Rapid Test Result Panel Training - B

- 1) **INV.** Test line appears above the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 2) **INV.** No test lines appear in the “T” or “C” designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 3) **INV.** Test lines appear outside the “T” and “C” designated areas. While on appearance, it would seem that a PRELIMINARY POSITIVE could be interpreted, the registration of the test lines are not in alignment with the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 4) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 5) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.

# OraQuick *ADVANCE*® Training Answer Key

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## OraQuick *ADVANCE*® Rapid Test Result Panel Training - B

- 6) **NR.** Test line appears only in the “C” designated area, indicating no detection of HIV-1 and/or HIV-2 antibodies are present at the time the test was conducted.
- 7) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HIV-1 and/or HIV-2 antibodies have been detected. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HIV virus.
- 8) **INV.** Test line appears below the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 9) **INV.** Test line appears only in the “T” designated area. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 10) **INV.** No test lines appear in the “T” or “C” designated areas. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.

## OraQuick *ADVANCE*® Rapid Test Result Panel Training - C

- 1) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 2) **INV.** No test lines appear in the “T” or “C” designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 3) **INV.** Test line appears above the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 4) **INV.** Test lines appear outside the “T” and “C” designated areas. While on appearance, it would seem that a PRELIMINARY POSITIVE could be interpreted, the registration of the test lines are not in alignment with the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 5) **R.** Test lines appear in the “T” and “C” designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 6) **INV.** No test lines appear in the “T” or “C” designated areas. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 7) **INV.** Test line appears only in the “T” designated area. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 8) **INV.** Test line appears below the “C” designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 9) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HIV-1 and/or HIV-2 antibodies have been detected. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HIV virus.
- 10) **NR.** Test line appears only in the “C” designated area, indicating no detection of HIV-1 and/or HIV-2 antibodies are present at the time the test was conducted.

# OraQuick *ADVANCE*® Training Answer Key

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## OraQuick *ADVANCE*® Rapid Test Result Panel Training - D

- 1) **INV.** Test lines appear outside the "T" and "C" designated areas. While on appearance, it would seem that a PRELIMINARY POSITIVE could be interpreted, the registration of the test lines are not in alignment with the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 2) **INV.** Test line appears above the "C" designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 3) **INV.** Test line appears only in the "T" designated area. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 4) **R.** Test lines appear in the "T" and "C" designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 5) **R.** Test lines appear in the "T" and "C" designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 6) **INV.** No test lines appear in the "T" or "C" designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 7) **R.** Test lines appear in the "C" and "T" designated areas, indicating that the presence of HIV-1 and/or HIV-2 antibodies have been detected. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HIV virus.
- 8) **NR.** Test line appears only in the "C" designated area, indicating no detection of HIV-1 and/or HIV-2 antibodies are present at the time the test was conducted.
- 9) **INV.** No test lines appear in the "T" or "C" designated areas. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 10) **INV.** Test line appears below the "C" designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.

## OraQuick *ADVANCE*® Rapid Test Result Panel Training - E

- 1) **NR.** Test line appears only in the "C" designated area, indicating no detection of HIV-1 and/or HIV-2 antibodies are present at the time the test was conducted.
- 2) **INV.** No test lines appear in the "T" or "C" designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 3) **INV.** Test line appears below the "C" designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 4) **R.** Test lines appear in the "T" and "C" designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.



## OraQuick *ADVANCE*® Training Answer Key

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### OraQuick *ADVANCE*® Rapid Test Result Panel Training - E

- 5) **INV.** No test lines appear in the "T" or "C" designated areas. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 6) **INV.** Test lines appear outside the "T" and "C" designated areas. While on appearance, it would seem that a PRELIMINARY POSITIVE could be interpreted, the registration of the test lines are not in alignment with the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 7) **R.** Test lines appear in the "C" and "T" designated areas, indicating that the presence of HIV-1 and/or HIV-2 antibodies have been detected. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HIV virus.
- 8) **R.** Test lines appear in the "T" and "C" designated areas. The test is interpreted as a PRELIMINARY POSITIVE. A confirmatory test should be ordered.
- 9) **INV.** Test line appears only in the "T" designated area. This result means there was a problem running the test, either related to the specimen or to the Device. Repeat the test with a new Pouch and a new sample.
- 10) **INV.** Test line appears above the "C" designated area. No interpretation can be made. Repeat the test with a new Pouch and a new sample.

## Proficiency Testing Panel Results

### Specimen Proficiency Panel Interpretation:

For each specimen, indicate the result with a checkmark for either REACTIVE, NON-REACTIVE, or INVALID.

Assay Lot #: \_\_\_\_\_

Specimen A: ☐ REACTIVE ☐ NON-REACTIVE ☐ INVALID

Specimen B: ☐ REACTIVE ☐ NON-REACTIVE ☐ INVALID

Specimen C: ☐ REACTIVE ☐ NON-REACTIVE ☐ INVALID

Specimen D: ☐ REACTIVE ☐ NON-REACTIVE ☐ INVALID

Specimen E: ☐ REACTIVE ☐ NON-REACTIVE ☐ INVALID

To be completed by study monitor:

☐ CORRECT ☐ INCORRECT

☐ CORRECT ☐ INCORRECT

☐ CORRECT ☐ INCORRECT

☐ CORRECT ☐ INCORRECT

☐ CORRECT ☐ INCORRECT

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



## Investigational and Remedial Action on Unacceptable Proficiency Testing

Date of Investigation: \_\_\_\_\_ Clinic Name/Site Location: \_\_\_\_\_

Prepared by: \_\_\_\_\_

Client Sample: <input type="checkbox"/> Yes <input type="checkbox"/> No	Control Sample: <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Testing:	Time of Testing:
Lot # of Test Device:	Exp. Date of Test Device:
Unacceptable (Reported) Result:	
Acceptable Result Range:	
Day of Testing - Quality Control Results Reviewed: <input type="checkbox"/> Yes <input type="checkbox"/> Acceptable <input type="checkbox"/> Not Acceptable Indicate Corrective Action:	
Clerical/Transcription Review: <input type="checkbox"/> Acceptable <input type="checkbox"/> Not Acceptable Indicate Corrective Action:	
Was Patient Reported Results Affected? <input type="checkbox"/> No, <i>(skip to next section)</i> <input type="checkbox"/> Yes Indicate Corrective Action:	
Classification of Problem: <input type="checkbox"/> Clerical <input type="checkbox"/> Technical <input type="checkbox"/> Methodology <input type="checkbox"/> Problem with Client  <input type="checkbox"/> Training Issue <input type="checkbox"/> No Explanation	
Conclusions:	
Corrective Actions/System Change(s) To Prevent Recurrence:	
Supervisor:	Date:
Lab Director:	Date:

Upon Completion - This Record Must be Maintained According to Local Regulations

## Clinic Communication and Complaint Log

Clinic Name/Site Location:		
Date Reported:	Time:	Initiated By:
Source of Communication/Complaint:		
Date of Occurrence:	Time:	
Narrative of Event (If necessary):		
Immediate Corrective Action Taken:		
Does the written procedure cover how to deal with this event? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable		
<b>*If No – Procedure must be updated within fifteen days from date of event.</b>		
If Yes – Was the written procedure followed?  <input type="checkbox"/> Yes <input type="checkbox"/> No	If No – Why not? Explain Below	
Follow-up Activities Required?  <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes-Indicate what and date to be completed below	
Form Completed by:	Date:	
Signature	Date:	

Upon Completion - This Record Must be Maintained According to Local Regulations

## Clinic Communication and Complaint Log

Clinic Name/Site Location: <b>Schoectady Women's Health Clinic - Schoectady, New York</b>		
Date Reported: <b>9/5/03</b>	Time: <b>9:50 a.m.</b>	Initiated By: <b>Josephine Parker</b>
Source of Communication/Complaint: <b>Kathy DeWitt's (#1234581) Rapid HIV Screening Test revealed a "Preliminary Positive" test result.</b>		
<b>Client signed Informed Consent Form and refuses follow-up for Confirmatory Test.</b>		
Date of Occurrence: <b>9/5/03</b>	Time: <b>9:00 a.m.</b>	
Narrative of Event (If necessary): <b>Explained to Ms. DeWitt's the importance of receiving a confirmatory test for a conclusive diagnosis as well as</b>		
<b>including importance of receiving future medical care and treatment. Reviewed availability of local programs</b>		
<b>and further counseling information. Re-emphasized the issues of protection from potential exposure to partner.</b>		
Immediate Corrective Action Taken:		
Does the written procedure cover how to deal with this event? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable *If No – Procedure must be updated within fifteen days from date of event.		
If Yes – Was the written procedure followed?  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No – Why not? Explain Below	
Follow-up Activities Required?  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If Yes-Indicate what and date to be completed below	
Form Completed by: <b>Josephine Parker</b>	Date: <b>9/5/10</b>	
Signature <b>Diane Rancer - Supervisor</b>	Date: <b>9/5/10</b>	

Upon Completion - This Record Must be Maintained According to Local Regulations

Name \_\_\_\_\_

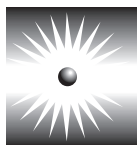
## Rapid HIV Testing

Performance	Yes	No
1. Looks at triage sheet to determine if patient wants HIV testing		
2. Gathers/arranges all materials correctly		
3. Performs informed consent		
4. Gathers/arranges all materials		
5. Examines test kit pouch (unopened, room temperature, absorbent packet)		
6. Correctly explains procedure of oral swabbing to the patient		
a. Touch the handle ONLY		
b. Place flat pad above the teeth against the outer gum		
c. Gently swab completely around the outer gums, both upper and lower, one time around		
7. Did NOT remove test kit until ready to insert into patient mouth		
8. Did NOT touch flat pad when using test kit		
9. Successfully swabs gums (may be performed by the tester or the patient)		
10. Successfully inserts the test kit back into the Divided Pouch prior to transport to the lab (may be performed by the tester or the patient)		
11. Documents or makes notation of time of swabbing		
12. Returns to lab space		
13. Successfully opens and positions vial in stand in lab (no spillage, vial to bottom of stand)		
14. Successfully places the Test Device into the developer solution (no spillage, window forward, pad touches bottom of vial) within 10 minutes of swabbing.		
15. Affixes patient label to front of test unit (does not cover holes on back of test device)		
16. Correctly logs patient in log book		
a. Places patient sticker in log book		
b. Records lot number and expiration date		
c. Records temperature in log book		
d. Records swabbing time		
e. Records start time		
f. Records time for test interpretation		
g. Completes remainder of log		
17. Utilizes timer		
18. Correctly interprets test within 20-40 minute timeframe		
19. Documents results in nursing notes		
20. Completes Wellsoft HIV information section		
21. For NEGATIVE tests, discloses results to patient using appropriate handouts		
22. For PRELIMINARY POSITIVE tests, correctly utilizes the preliminary positive packet and notifies MD		

Satisfactorily completed procedure.

\_\_\_\_\_  
Evaluator Signature

\_\_\_\_\_  
Date



**OraSure Technologies, Inc.**

## **OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Customer Letter**

Dear Customer,

Thank you for deciding to use the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The sale, distribution, and use of this product is restricted as described in the product insert. By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the following restrictions on the sale, distribution, and use of the device:

1. Sale of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is restricted to clinical laboratories
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met<sup>1-3</sup>; and
  - where there is assurance that operators will receive and use the instructional materials.
2. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is approved for use only by an agent of a clinical laboratory.
3. Test subjects must receive the "Subject Information" pamphlet and pre-test counseling prior to specimen collection, and appropriate counseling when test results are provided.
4. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is not approved for use to screen blood or tissue donors.

The package insert for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test contains warnings and precautions, restrictions on the sale, distribution, and use of the device, and information about how the device works, how to use the device, interpretation of results, and limitations of the procedure. The "Subject Information" pamphlet provides subjects with information about the limitations of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and the meaning of a preliminary positive or negative test result with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, as well as general information about HIV and AIDS. You should review all of these materials yourself.

If you have any questions, please call us toll-free at 1-800-ORASURE (1-800-672-7873) or 1-800-869-3538 and ask for customer service.

Sincerely,

OraSure Technologies' Customer Service

### References

1. CLSI Document GP2-A4, Clinical Laboratory Technical Procedure Manuals
2. CLSI Document GP27-A, Using Proficiency Testing (PT) to Improve the Clinical Laboratory
3. CLSI Document AST2-A, Point-of-Care In Vitro (IVD) Testing



**Read this package insert completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results. Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.<sup>5,9</sup>**

#### **COMPLEXITY: WAIVED**

for Oral Fluid, Fingerstick Whole Blood and Venipuncture Whole Blood. Any modification by the laboratory to the test system or FDA approved test system instructions will result in the test no longer meeting the requirements for waived category.

#### **COMPLEXITY: MODERATE**

for Plasma.

#### **NAME AND INTENDED USE**

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood, venipuncture whole blood and plasma specimens. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

#### **RESTRICTIONS**

- **Sale of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is restricted to clinical laboratories**
  - **that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and**
  - **where there is assurance that operators will receive and use the instructional materials.**
- **The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the “Subject Information” pamphlet prior to specimen collection and appropriate information when test results are provided.**
- **The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is not approved for use to screen blood or tissue donors.**

#### **SUMMARY AND EXPLANATION OF THE TEST**

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC) and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). The first AIDS-related virus, HIV-1 (also known as HTLV-III, LAV-1 and ARV) has been isolated from patients with AIDS and from healthy persons at high risk for AIDS.<sup>1,2</sup> Genetic analysis of HIV-1 isolates has documented the existence of subtypes. To date, eight HIV-1 subtypes (A through H), designated as Group M, have been identified world-wide in addition to the highly divergent HIV-1 isolates from AIDS patients in Cameroon, designated as Group O.<sup>3</sup> A closely related but distinct second type of pathogenic human immunodeficiency retrovirus, designated HIV-2 (formerly LAV-2), has been isolated from West African patients with AIDS. HIV-2 has been shown to share a number of conserved sequences with HIV-1, but serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample.

HIV is known to be transmitted by sexual contact, by exposure to blood (including sharing contaminated needles and syringes) or by contaminated blood products, or it may be transmitted from an infected mother to her fetus during the prenatal period. Individuals infected with HIV produce antibodies against the HIV viral proteins. Testing for the presence of antibodies to HIV in bodily fluids (e.g., blood, oral fluid, and urine) is an accurate aid in the diagnosis of HIV infection. However, the implications of seropositivity must be considered in a clinical context. For example, in neonates, the presence of antibodies to HIV is indicative of exposure to HIV, but not necessarily of HIV infection, due to the acquisition of maternal antibodies that may persist for up to eighteen months. Conversely, absence of antibody to HIV cannot be taken as absolute proof that an individual is free of HIV infection or incapable of transmitting the virus. An antibody response to a recent exposure may take several months to reach detectable levels. HIV has been isolated from asymptomatic, seronegative individuals presumably before seroconversion following exposure.

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using a Western blot test. Results are typically reported within 48 hours to 2 weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HIV diagnosis. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

Using a rapid HIV test increases the number of HIV-infected persons who may be diagnosed. The Centers for Disease Control and Prevention (CDC) estimates that nearly one third of the estimated 900,000 HIV-infected persons in the United States do not know their HIV status. As a result, they cannot benefit from early intervention with effective antiviral therapy. Rapid HIV testing addresses this

issue by providing results during the initial visit and enabling immediate counseling. Additionally, for pregnant women who do not know their HIV status at the time of delivery, rapid HIV testing permits therapy to be initiated for these mothers during labor, and to their infants post partum, substantially reducing the chance that the infants will become infected with HIV. Likewise, rapid HIV testing is instrumental in the decision to initiate treatment for health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 "needlestick injuries" occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results.

## BIOLOGICAL PRINCIPLES OF THE TEST

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid, whole blood obtained from a finger puncture or a venipuncture, and plasma. The OraQuick *ADVANCE*® rapid test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The OraQuick *ADVANCE*® rapid test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

An oral fluid specimen is collected using the flat pad on the test device, followed by the insertion of the test device into the vial of developer solution. A fingerstick whole blood, venipuncture whole blood or plasma specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

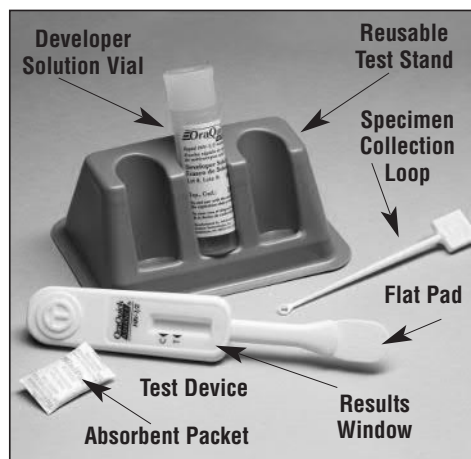
Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1 and/or HIV-2 (refer to the *Test Result and Interpretation of Test Result* section below).

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen. No precision pipeting, predilutions, or specialized instrumentation are required to perform the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

## MATERIALS PROVIDED

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kits are available in the following packaging configurations:

Kit Size	100 Count	25 Count
Divided Pouches, each containing: Test Device (1) Absorbent Packet (1) Developer Solution Vial (1) (each vial contains 1 mL of a phosphate buffered saline solution containing polymers and an antimicrobial agent)	100	25
Reusable Test Stands	10	5
Specimen Collection Loops	100	25
Subject Information Pamphlets	100	25
Package Insert	1	1
Customer Letter	1	1



## MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls

Package contains HIV-1 Positive Control (1 vial, black cap, 0.2 mL), HIV-2 Positive Control (1 vial, red cap, 0.2 mL) and Negative Control (1 vial, white cap, 0.2 mL), and a Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes

Clean, disposable, absorbent workspace cover

Biohazard waste container

### Additional items required for fingerstick and venipuncture whole blood collection, and plasma specimens:

Antiseptic wipe

Sterile lancet to obtain a fingerstick whole blood specimen, or materials required to obtain a venipuncture whole blood specimen

Sterile gauze pads

Latex, vinyl or nitrile disposable gloves (optional for oral fluid testing)

Centrifuge to process a plasma specimen

## WARNINGS

### For *in vitro* Diagnostic Use

1. **Read the package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.**
2. **Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.<sup>5,9</sup>**
3. **FDA has approved this kit for use with oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens only. Use of this test kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.**
4. **This test should be performed at temperatures in the range of (15°- 37°C, 59°- 99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°- 37°C, 59°- 99°F) before performing testing.**
5. **If the test kit is stored at temperatures outside of ambient temperature (2°- 27°C, 35°- 80°F), or used outside of the operating temperature (15°- 37°C, 59°- 99°F), use the Kit Controls to ensure performance of the test.**
6. **Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.**

## PRECAUTIONS

### Safety Precautions

1. Handle blood specimens and materials contacting blood specimens as if capable of transmitting infectious agents.
2. Do not drink, eat, or smoke in areas where specimens are being handled or testing is being performed.
3. Wear disposable gloves while handling blood specimens and performing testing of blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
4. Oral fluid is not considered potentially infectious unless it contains blood.<sup>8</sup> Use of gloves for oral fluid testing is optional. Test administrators with breaks in the skin (cuts, abrasions, or dermatitis) should wear gloves when performing oral fluid testing. Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
5. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. Lancets and venipuncture materials should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
6. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant<sup>4</sup>. Bleach solutions should be made fresh each day.
7. For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings"<sup>5,9</sup> and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis".<sup>8</sup>

### Handling Precautions

1. Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). **Do not reuse any of these test components.**
2. Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
3. Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
4. Avoid microbial contamination and exercise care in handling the kit components.
5. To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the fingerstick whole blood, venipuncture whole blood or plasma sample.
6. When collecting oral fluid specimens the Test Device must be inserted into the Developer Solution Vial within 30 minutes of collection. A Test Device containing an oral fluid specimen that is not inserted into the Developer Solution Vial within 10 minutes of collection should be either stored on a flat surface or returned to the Divided Pouch after the desiccant has been removed from the Divided Pouch. For a 10-30 minute delay in insertion, return the Test Device containing the oral fluid specimen to the Divided Pouch after the desiccant has been removed from the Divided Pouch. Ensure that the Divided Pouch containing the Test Device is kept in a horizontal position until the Test Device is inserted into the Developer Solution Vial.
7. Adequate lighting is required to read a test result.



## STORAGE INSTRUCTIONS

Store unused OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Tests unopened at 2°-27°C (35°-80°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°- 37°C, 59°- 99°F) before opening.

## DIRECTIONS FOR USE

### SET UP YOUR WORKSPACE

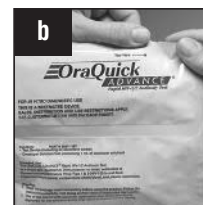
- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15°- 37°C; 59°- 99°F) before use.
- Refer to the *External Quality Control* section in this package insert to determine when the Kit Controls should be run.
- Cover your workspace with a clean, disposable, absorbent workspace cover.
- Set an OraQuick *ADVANCE*® Reusable Test Stand ("Stand") up on your workspace cover. Use only the stand provided.
- Put on your disposable gloves as required in accordance with the *Safety Precautions* section in this package insert.

**Prior to testing provide the "Subject Information" pamphlet to the person being tested.**

### GENERAL TEST PREPARATION

1. Open the two chambers of the OraQuick *ADVANCE*® Divided Pouch ("Pouch") by tearing at the notches on the top of each side of the Pouch (see picture a and b). To prevent contamination, leave the Test Device ("Device") in the Pouch until you are ready to use it.
2. Remove the Developer Solution Vial ("Vial") from the Pouch. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off. Set the cap on your workspace cover.
3. Slide the Vial into the top of one of the slots in the Stand. **DO NOT** force the vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the stand (see picture c).

Two Chambers



**NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials. Doing so may cause an Invalid result.**

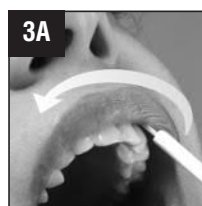
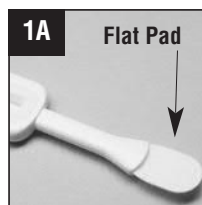
## SPECIMEN COLLECTION AND TESTING PROCEDURE

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test can be used for testing oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens. Refer to the specific testing procedure below.

### ORAL FLUID PROCEDURE

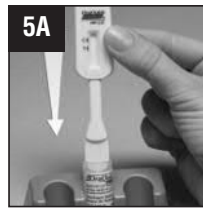
#### STEP 1: COLLECT

1. Ensure prior to testing that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.
2. Have the person being tested remove the Device from its Pouch. **DO NOT** allow the person to touch the Flat Pad (see picture 1A). Check to make sure that an Absorbent Packet is included with the Device (see picture 2A). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
3. Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad (see pictures 3A and 4A). **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. **NOTE:** Both sides of the Flat Pad may be used during this procedure.



## STEP 2: TEST

1. Insert the Flat Pad of the Device all the way into the Vial (see picture 5A). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 6A).
2. Start timing the test (see picture 7A). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 8A). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
3. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.



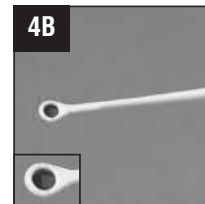
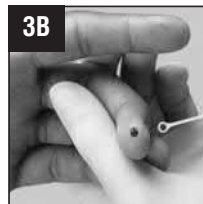
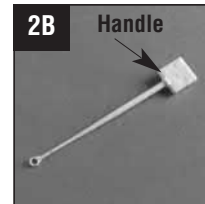
## FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE WHOLE BLOOD PROCEDURE

### STEP 1: COLLECT

Whole blood specimens may be collected either by fingerstick (see Step 1.A) or by venipuncture (see Step 1.B).

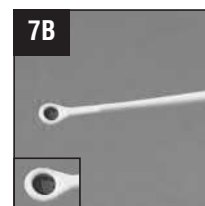
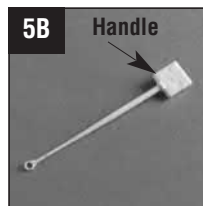
#### STEP 1.A: FINGERSTICK WHOLE BLOOD

1. Using an antiseptic wipe, clean the finger of the person being tested. After cleansing the skin puncture site, allow the area to air dry, so the antiseptic action of the alcohol can take effect. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see picture 1B). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture 2B). Put the "rounded" end of the Loop on the drop of blood (see picture 3B). Make sure that the Loop is completely filled with blood (see picture 4B). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.



#### STEP 1.B: VENIPUNCTURE WHOLE BLOOD

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2°-30°C (35°-86°F) for up to 5 days. Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture 5B). Put the "rounded" end of the Loop into the tube of blood (see picture 6B). Make sure that the Loop is completely filled with blood (see picture 7B). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.



### STEP 2: MIX

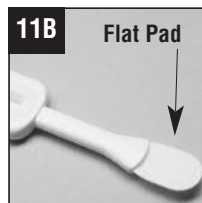
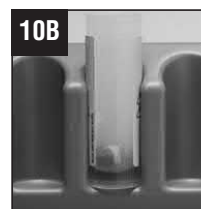
1. Immediately insert the blood-filled end of the Loop all the way into the Vial (see picture 8B). Use the Loop to stir the blood sample in the Developer Solution ("Solution") (see picture 9B). Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.



2. Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (see picture 10B). If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.

### STEP 3: TEST

1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture 11B). Check to make sure that an Absorbent Packet is included with the Device (see picture 12B). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture 13B). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 14B).
3. Start timing the test (see picture 15B). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 16B). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
4. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.

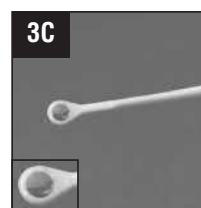
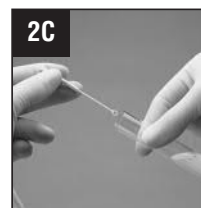
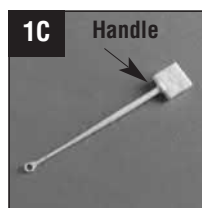


### PLASMA PROCEDURE

**NOTE:** Testing of plasma samples may only be performed by laboratories certified to perform Moderate Complexity tests.

#### STEP 1: COLLECT

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing EDTA (lavender top) anticoagulant. **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the specimen may be stored as whole blood for up to 5 days at 2°-30°C (35°-86°F) or as plasma for up to 7 days at 2°-8°C (35°-46°F).
2. Centrifuge the tube of blood [1000-1300 x g, for approximately 5 minutes, no refrigeration required] to separate the cells from the plasma. Carefully uncap the tube by gently rocking the stopper towards you so that it vents away from you.
3. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture 1C). Put the "rounded" end of the Loop into the tube of plasma (see picture 2C). Make sure that the Loop is completely filled with plasma (see picture 3C). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the plasma sample.



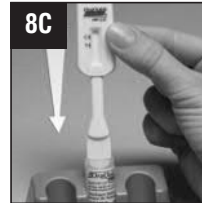
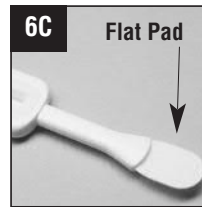
#### STEP 2: MIX

1. Immediately insert the plasma-filled end of the Loop all the way into the Vial (see picture 4C). Use the Loop to stir the plasma sample in the Developer Solution ("Solution") (see picture 5C). Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.



### STEP 3: TEST

1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture 6C). Check to make sure that an Absorbent Packet is included with the Device (see picture 7C). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture 8C). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 9C).
3. Start timing the test (see picture 10C). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 11C). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
4. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.



### GENERAL TEST CLEAN-UP

1. Dispose of the used test materials in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

### QUALITY CONTROL

#### Built-in Control Features

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control ("C") area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is reactive or non-reactive. (Refer to *Test Result and Interpretation of Test Result* section below.)

#### External Quality Control

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls are available separately for use only with the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Positive Controls will produce a reactive test result and have been manufactured to produce a very faint Test ("T") line. The Negative Control will produce a non-reactive test result. (Refer to *Test Result and Interpretation of Test Result* section below.) Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test.

#### Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°- 27°C (35°- 80°F),
- If the temperature of the testing area falls outside of 15°- 37°C (59°- 99°F), and
- At periodic intervals as dictated by the user facility.

Refer to the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls package insert for instructions on the use of these reagents. It is the responsibility of each laboratory using the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Contact OraSure Technologies' Customer Service if the Kit Control reagents do not produce the expected results.

### TEST RESULT AND INTERPRETATION OF TEST RESULT

#### Refer to the Result Window on the Test Device.

#### NON-REACTIVE

The diagram at the right shows an example of a **Non-Reactive** test result.

A test is Non-Reactive if:

- a reddish-purple line appears next to the triangle labeled "C", **and NO**
- line appears next to the triangle labeled "T".

A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies**. Follow CDC guidelines to inform the test subject of the test result and its interpretation.<sup>6,7</sup>



## REACTIVE

The diagrams at the right show examples of a **Reactive** test result.

A test is **Reactive** if:

a reddish-purple line appears next to the triangle labeled “C” **and** a reddish-purple line appears next to the triangle labeled “T”. One of these lines may be darker than the other.

**NOTE:** The test is **Reactive** if **any** reddish-purple line appears next to the “T” triangle **and** next to the “C” triangle, no matter how faint these lines are.

A **Reactive** test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies**. Follow CDC guidelines to inform the test subject of the test result and its interpretation.<sup>6,7</sup>



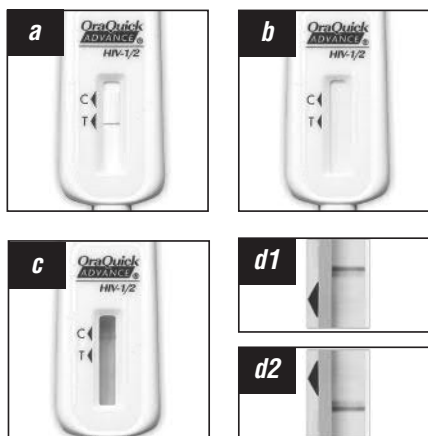
## INVALID

The diagrams at the right show examples of an **Invalid** test result.

A test is **Invalid** if any of the following occurs:

- **NO** reddish-purple line appears next to the triangle labeled “C” (see picture a and b), or
- a red background in the Result Window makes it difficult to read the result after 20 minutes (see picture c), or
- if any of the lines are NOT inside the “C” or “T” triangle areas (see picture d1 and d2)

An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Test Device. An **Invalid** result cannot be interpreted. **Repeat the test with a new Divided Pouch and a new oral fluid, fingerstick or venipuncture whole blood, or plasma sample. Contact OraSure Technologies’ Customer Service if you are unable to get a valid test result upon repeat testing.**



## LIMITATIONS OF THE TEST

1. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
3. This test is approved by FDA for use with oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens only. Use of other types of specimens, testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than EDTA, sodium heparin, or sodium citrate, or testing of plasma specimens collected using a tube containing an anticoagulant other than EDTA may not yield accurate results.
4. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
5. Clinical data has not been collected to demonstrate the performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in persons under 12 years of age.
6. A reactive result using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
7. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
8. A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
9. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.



## PERFORMANCE CHARACTERISTICS

### SENSITIVITY

#### DETECTION OF ANTIBODIES TO HIV-1 IN SPECIMENS FROM INDIVIDUALS INFECTED WITH HIV-1

##### ORAL FLUID

A sensitivity study was performed at eight clinical trial sites using freshly obtained oral fluid specimens collected from 767 individuals reported to be infected with HIV-1. Of the 767 specimens that were identified as seropositive using licensed confirmatory testing, 762 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 1.

A separate study was performed at four clinical trial sites using freshly obtained oral fluid specimens collected from 3150 previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 1. Of the 73 specimens that were identified as seropositive using licensed confirmatory testing, 72 were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

**TABLE 1**  
**Detection of Antibody to HIV-1 in Oral Fluid Specimens from HIV-1 Seropositive Individuals**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive <sup>1</sup>
Known HIV-1 Positive	767	762	764	767
High-Risk	3150	72 <sup>2</sup>	74 <sup>3</sup>	73
TOTAL	3917	834	838	840

<sup>1</sup> Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by licensed immunofluorescence assay (IFA).

<sup>2</sup> Eight additional specimens were OraQuick *ADVANCE*® false positive (see Table 7).

<sup>3</sup> One specimen was EIA false positive, with a negative Western blot.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be  $834/840 = 99.3\%$  (95% C.I. = 98.4% - 99.7%).

##### PLASMA

A sensitivity study was performed at eleven clinical trial sites using EDTA-plasma specimens collected from 891 individuals reported to be infected with HIV-1. Of the 891 specimens that were identified as seropositive using licensed confirmatory testing, 887 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 2.

A separate study was performed at six clinical trial sites using EDTA-plasma specimens collected from 533 previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 2. All of the 14 specimens that were identified as seropositive using licensed confirmatory testing, were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

**TABLE 2**  
**Detection of Antibody to HIV-1 in Plasma Specimens from HIV-1 Seropositive Individuals**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive <sup>1</sup>
Known HIV-1 Positive	891	887	891	891
High-Risk	533	14 <sup>2</sup>	14	14
TOTAL	1424	901	905	905

<sup>1</sup> Confirmation performed by licensed HIV-1 Western blot, confirmation of indeterminate Western blot results by radioimmunoprecipitation assay (RIPA) or licensed IFA.

<sup>2</sup> One additional specimen was OraQuick *ADVANCE*® false positive (see Table 8).

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be  $901/905 = 99.6\%$  (95% C.I. = 98.9% - 99.8%).

### FINGERSTICK WHOLE BLOOD

A sensitivity study was performed at eight clinical trial sites using freshly obtained fingerstick whole blood samples from 481 individuals known to be infected with HIV-1 and 40 AIDS patients. Of the 521 specimens that were repeatedly reactive using a licensed EIA and positive by Western blot, 519 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 3.

A separate study was performed at seven clinical trial sites using 625 freshly obtained fingerstick whole blood samples from previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 3. Of the 625 specimens tested, 20 were repeatedly reactive using a licensed EIA, of which 17 were positive by Western blot. These same 17 specimens gave a reactive result using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

**TABLE 3**  
**Detection of Antibody to HIV-1 in Fingerstick Whole Blood Samples from Patients with AIDS and from HIV-1 Seropositive Individuals**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive <sup>1</sup>
AIDS	40	40	40	40
Known HIV-1 Positive	481	479	481	481
High-Risk	625	17	20 <sup>2</sup>	17
TOTAL	1146	536	541	538

<sup>1</sup> Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA.

<sup>2</sup> Two specimens were negative and one was indeterminate on Western blot with a negative RIPA.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be  $536/538 = 99.6\%$  (95% C.I. = 98.5% - 99.9%).

### Reactivity with HIV-1 Specimens From Various Geographic Regions

To assess the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test for HIV-1 variants from various geographic regions, 215 confirmed HIV-1 antibody-positive serum/plasma specimens were obtained from various parts of the world. Of these 215 specimens, 214 were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. One confirmed HIV-1 antibody-positive specimen from China was non-reactive using the OraQuick *ADVANCE*® test. An additional 13 specimens representing HIV-1 Subtypes A, B, C, D, F, and G, and Group O were tested and reactive on OraQuick *ADVANCE*®.

### Reactivity with HIV-1 Seroconversion Panels

Eleven HIV-1 seroconversions panels were tested in comparison with licensed anti-HIV EIA tests. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 69 specimens. The results of this study are shown in Table 4. In this study, the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting seroconversion similar to currently available FDA licensed EIAs.

**TABLE 4**  
**Comparison of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests**  
**Using Seroconversion Panels**

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Relative Day of Bleed	OraQuick <i>ADVANCE</i> ® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
K	1	NR	NR	NR	NR	NR	NR
	7	NR	NR	NR	NR	NR	NR
	9	NR	NR	NR	NR	NR	NR
	14	<b>R</b>	NR	<b>RR</b>	NR	NR	NR
	16	<b>R</b>	NR	<b>RR</b>	NR	NR	NR
	21	<b>R</b>	NR	<b>RR</b>	NR	<b>RR</b>	<b>RR</b>
	23	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	30	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	34	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	37	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
N	1	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	NR	NR
	5	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	<b>RR</b>	NR
	8	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	<b>RR</b>	NR
	26	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	32	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
Q	1	NR	NR	NR	NR	NR	NR
	54	NR	NR	NR	NR	NR	NR
	58	NR	NR	NR	NR	NR	NR
	61	NR	NR	<b>RR</b>	NR	NR	NR
	66	<b>R</b>	NR	<b>RR</b>	NR	NR	NR
	68	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	NR	NR
	73	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
R (M)	3	NR	NR	<b>RR</b>	NR	NR	NR
	8	NR	NR	<b>RR</b>	NR	NR	NR
	14	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	16	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	22	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
S	1	NR	NR	NR	NR	NR	NR
	10	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	NR	NR
	12	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	<b>RR</b>	NR
W	1	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	13	NR	NR	NR	NR	NR	NR
	15	NR	NR	NR	NR	NR	NR
	29	NR	NR	NR	NR	NR	NR
	31	NR	NR	NR	NR	NR	NR
	36	NR	NR	NR	NR	NR	NR
	38	NR	NR	NR	NR	NR	NR
	48	NR	NR	<b>RR</b>	NR	NR	NR
	85	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	87	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	146	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
	162	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>
AB	1	NR	NR	NR	NR	NR	NR
	29	NR	NR	<b>RR</b>	NR	NR	NR
	34	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	NR	NR
	36	<b>R</b>	<b>RR</b>	<b>RR</b>	NR	NR	<b>RR</b>
	41	<b>R</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>	<b>RR</b>



Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Relative Day of Bleed	OraQuick <i>ADVANCE</i> ® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
AC	1	NR	NR	NR	NR	NR	NR
	112	NR	NR	RR	NR	NR	NR
	121	R	RR	RR	RR	RR	RR
	126	R	RR	RR	RR	RR	RR
	131	R	RR	RR	RR	RR	RR
AE	1	NR	NR	NR	NR	NR	NR
	4	NR	NR	NR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	11	NR	RR	RR	NR	RR	NR
AF	1	NR	NR	NR	NR	NR	NR
	3	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	10	NR	NR	NR	NR	NR	NR
	16	NR	NR	NR	NR	NR	NR
	29	R	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	RR	RR
	36	R	RR	RR	RR	RR	RR
AI	1	NR	NR	NR	NR	NR	NR
	8	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	RR	RR

NR = Non-Reactive; R = Reactive; RR = Repeatedly Reactive

#### Reactivity with HIV-1 Low Titer Panels

Two low titer HIV-1 antibody panels were tested in comparison with licensed anti-HIV EIA tests. The low titer antibody panels consisted of 30 serum/plasma specimens. The results of this study are shown in Table 5. In this study, the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting antibodies to HIV-1 similar to currently available FDA licensed EIAs.

**TABLE 5**  
**Comparison of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests Using Low Titer HIV-1 Antibody Panels**

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Member	OraQuick <i>ADVANCE</i> ® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT106	1	R	RR	RR	RR	RR	RR
	2	NR	NR	RR	NR	NR	NR
	3	R	RR	RR	RR	RR	RR
	4	R	RR	RR	RR	RR	RR
	5	R	RR	RR	RR	RR	RR
	6	NR	NR	NR	NR	NR	NR
	7	R	RR	RR	RR	RR	RR
	8	NR	RR	RR	NR	NR	NR
	9	R	RR	RR	RR	RR	RR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	NR	RR
	13	R	RR	RR	RR	RR	RR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

Specimen Information		OraQuick <i>ADVANCE</i> ® Test	Licensed Anti-HIV EIA Tests				
Panel	Member		EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT107	1	NR	NR	RR	RR	NR	NR
	2	R	NR	RR	RR	RR	NR
	3	R	NR	RR	NR	NR	NR
	4	R	RR	RR	RR	RR	NR
	5	NR	NR	NR	NR	NR	NR
	6	R	RR	RR	RR	RR	NR
	7	NR	NR	RR	RR	NR	NR
	8	NR	NR	RR	NR	RR	NR
	9	NR	NR	RR	NR	NR	NR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	RR	RR	RR
	12	NR	NR	RR	NR	NR	NR
	13	NR	NR	RR	RR	NR	NR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

NR = Non-Reactive; R = Reactive; RR = Repeatedly Reactive

#### Interfering Substances and Unrelated Medical Conditions

To assess the impact of unrelated medical conditions or interfering substances on the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 200 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 125 specimens with interfering substances were spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range (see list of medical conditions and interfering substances in Table 10 below). All spiked specimens gave reactive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay sensitivity. Venipuncture whole blood collected from 24 subjects, in each of 3 tubes containing one of three anticoagulants (EDTA, sodium heparin, and sodium citrate) was spiked with an HIV-1 positive specimen or an HIV-2 positive specimen to give a level of reactivity in the low positive range. The HIV-1 positive samples and the HIV-2 positive samples were then aliquoted and stored refrigerated (2°-8°C), at room temperature (18°C) or at elevated temperatures (30-33°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 7 days at 2°-30°C.

As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). None of these disease states, medical conditions or other factors interfered with test sensitivity. In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test sensitivity.

#### DETECTION OF ANTIBODIES TO HIV-2 IN SPECIMENS FROM INDIVIDUALS INFECTED WITH HIV-2

A total of 324 serum/plasma specimens reported to be HIV-2 antibody positive were obtained from various repository sources. Specimens were tested by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, an HIV-2 Western blot and HIV-2 specific PCR. A total of 6 specimens were not demonstrated to be positive for antibodies to HIV-1 or HIV-2, all of which were OraQuick *ADVANCE*® non-reactive. Two of the 6 negative specimens were repeatedly reactive by licensed anti-HIV-1/2 EIA, negative by licensed anti-HIV-2 EIA, and indeterminate by licensed HIV-1 Western blot and by an HIV-2 Western blot.

Of the remaining 318 specimens, 151 were positive on an HIV-2 Western blot and 50 were positive using an HIV-2 specific PCR. One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. One specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis. One specimen, while indeterminate on HIV-1 and HIV-2 Western blots, gave a positive result on an HIV-2 radioimmuno-precipitation assay (RIPA) and is also considered to be positive for antibodies to HIV-2. OraQuick *ADVANCE*® detected 201/201 (100%) of the specimens from individuals confirmed as positive for HIV-2 antibodies (see Table 6).

In a separate study, a total of 499 plasma specimens collected from an HIV-2 endemic area (Ivory Coast) were prepared as contrived whole blood and tested by OraQuick *ADVANCE*®, licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, and an HIV-2 Western blot. Table 6 shows a summary of the results. OraQuick *ADVANCE*® was reactive with all of the 27 specimens that were repeatedly reactive by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA and positive on licensed HIV-1 Western blot, and with all three specimens that were confirmed as positive for HIV-2 only by an HIV-2 Western blot. Two specimens were OraQuick *ADVANCE*® false positive.

**TABLE 6**  
**Detection of Antibody to HIV-2 in Samples from HIV-2 Seropositive Individuals and**  
**Individuals at High Risk of HIV-2 Infection**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed anti-HIV-2 EIA Repeatedly Reactive or HIV-2 PCR Positive	True HIV-2 Positive <sup>1</sup>
Known HIV-2 Positive	324 <sup>2</sup>	201	201 <sup>3</sup>	201 <sup>4</sup>
High-Risk	499	32	33	3
TOTAL	823	233	234	204

<sup>1</sup> Confirmation performed by HIV-2 Western blot, with RIPA confirmation of Indeterminate Western blot results.

<sup>2</sup> One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. In addition, one specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis.

<sup>3</sup> 151 specimens were tested with an anti-HIV-2 EIA alone. HIV-2 DNA or RNA PCR was performed on the remaining 50 specimens instead of EIA. All results were positive.

<sup>4</sup> One specimen was confirmed to be HIV-2 positive based on the positive results of an HIV-2 specific RIPA.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of the high risk population, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test for the detection of antibodies to HIV-2 in these studies was calculated to be 204/204 = 100% (95% C.I. = 98.2% - 100%).

In addition, 3 HIV-2 infected individuals located in the USA were tested by fingerstick whole blood and oral fluid OraQuick *ADVANCE*® tests. Fingerstick whole blood and oral fluid samples from all three subjects were reactive on the OraQuick *ADVANCE*® test.

## SPECIFICITY

### ORAL FLUID

A specificity study was performed at four clinical trial sites using freshly obtained oral fluid specimens collected from 605 previously unscreened individuals at low risk for HIV-1 infection. All of the 605 specimens were correctly non-reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. Of the 3077 HIV antibody-negative specimens from the four study sites that examined populations at high risk for HIV-1 infection, the OraQuick *ADVANCE*® test was non-reactive for 3069. The results are summarized in Table 7.

**TABLE 7**  
**Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Oral Fluid Specimens**  
**from Individuals Presumed to be Negative for HIV Infection**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative <sup>1</sup>
Low-Risk	605	605	599 <sup>2</sup>	605
High-Risk	3150	3069 <sup>3</sup>	3076 <sup>4</sup>	3077
TOTAL	3755	3674	3675	3682

<sup>1</sup> Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA or IFA.

<sup>2</sup> Six specimens were EIA false positive, five with a negative Western blot and one with an indeterminate blot which was confirmed negative by IFA.

<sup>3</sup> One additional specimen was OraQuick *ADVANCE*® false negative (see Table 1).

<sup>4</sup> One specimen was EIA false positive with a negative Western blot.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be 3674/3682 = 99.8% (95% C.I. = 99.6% - 99.9%).

### PLASMA

A specificity study was performed at seven clinical trial sites using EDTA-plasma specimens collected from 1102 previously unscreened individuals at low risk for HIV infection. All of the specimens, except for one, gave non-reactive results using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. In addition, 519 of the 520 HIV antibody-negative specimens from study sites that examined populations at high risk for HIV-1 infection also gave non-reactive results using the OraQuick *ADVANCE*® test. The results of this study are shown in Table 8.

**TABLE 8**  
**Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Plasma Specimens**  
**from Individuals Presumed to be Negative for HIV Infection**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative <sup>1</sup>
Low-Risk	1102	1101	1096 <sup>2</sup>	1102
High-Risk	534	519	516 <sup>3</sup>	520
TOTAL	1636	1620	1612	1622

<sup>1</sup> Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA or IFA.

<sup>2</sup> Six specimens were EIA false positive, five with a negative Western blot and one with an indeterminate blot which was confirmed negative by IFA.

<sup>3</sup> Four specimens were EIA false positive, with 1 negative and 3 indeterminate by Western blot, that confirmed negative by IFA.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be 1620/1622 = 99.9% (95% C.I. = 99.6% - 99.9%).

#### **FINGERSTICK WHOLE BLOOD**

A specificity study was performed at eight clinical trial sites using freshly obtained fingerstick whole blood samples from 1250 previously unscreened individuals at low risk for HIV-1 infection. In the course of this study, two specimens were confirmed to have antibodies to HIV-1 and were removed from the specificity calculation. All of the remaining specimens gave non-reactive results using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. In addition, all of the 608 HIV-1 antibody-negative specimens from the study sites that examined populations at high risk for HIV-1 infection also gave non-reactive results using the OraQuick *ADVANCE*® test. The results of this study are shown in Table 9.

**TABLE 9**  
**Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Fingerstick Whole Blood Specimens**  
**from Individuals Presumed to be Negative for HIV Infection**

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative <sup>3</sup>
Low-Risk	1250 <sup>1</sup>	1248	1247 <sup>2</sup>	1248
High-Risk	625	608	605	608
TOTAL	1875	1856	1852	1856

<sup>1</sup> Two specimens in the low-risk study that gave reactive results using the OraQuick *ADVANCE*® test, repeatedly reactive results using a licensed EIA, and positive results using a licensed Western blot were removed from the calculation of specificity.

<sup>2</sup> One specimen was EIA repeatedly reactive, Western blot negative.

<sup>3</sup> True negative status based on negative or indeterminate test results using a licensed Western blot.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be 1856/1856 = 100% (95% C.I. = 99.7% - 100%).

#### **INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS**

To assess the impact of unrelated medical conditions or interfering substances on the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 321 serum/plasma specimens from a variety of medical conditions unrelated to HIV infection and 119 specimens with interfering substances were analyzed. The results of this study are shown in Table 10. One specimen from subjects known to be positive for EBV, for HBV, or for rheumatoid factor, one from a multiparous woman, and three specimens from known HAV infected subjects gave false positive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay specificity. Venipuncture whole blood was collected from 24 HIV negative subjects, in each of 3 tubes containing one of the following anticoagulants: EDTA, sodium heparin, and sodium citrate. The samples were then aliquoted and stored either refrigerated (2°-8°C), at room temperature (18°C) or at elevated temperatures (30-33°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 5 days at 2-30°C (refer to Table 10).

**TABLE 10**  
**OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Reactivity with Specimens from Individuals with Potentially Interfering Medical Conditions and Specimens with Interfering Substances**

Medical Condition (n = 321)	OraQuick <i>ADVANCE</i> ® Results	
	Reactive	Non-Reactive
Multiparous women	1 <sup>2</sup>	14
Anti-nuclear antibody (ANA)	0	17
Lupus	0	15
Rheumatoid factor	1 <sup>2</sup>	17
Cytomegalovirus (CMV)	0	15
Epstein Barr virus (EBV)	1 <sup>2</sup>	14
Hepatitis A virus (HAV)	3 <sup>1</sup>	17
Hepatitis B virus (HBV)	1 <sup>2</sup>	16
Hepatitis C virus (HCV)	0	15
Human T-cell Lymphotropic virus Type I (HTLV-I)	0	15
Human T-cell Lymphotropic virus Type II (HTLV-II)	0	15
Rubella	0	15
IgG gammopathies	0	13
IgM gammopathies	0	12
Syphilis	0	15
Toxoplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Multiple transfusions	0	10
Hemophiliac	0	10
Herpes Simplex virus	0	5
Cirrhosis	0	5
Dialysis patient	0	4
Colon cancer	0	4
HTLV I/II	0	2
Chlamydia	0	3
Anti-scl or anti-rnp antibody	0	3
Breast cancer	0	1
Anti-DNA antibody	0	1
Gonorrhea	0	1
Interfering Substances (n = 211)		
Elevated Bilirubin	0	20
Elevated Hemoglobin	0	20
Elevated Triglycerides	0	20
Elevated Protein	0	20
Bacterially Contaminated	0	25
Visual Hemolysis (hemolytic)	0	5
Icteric	0	5
Lipemic	0	4
Sodium Heparin <sup>3</sup>	0	24
EDTA <sup>3</sup>	0	24
Sodium Citrate <sup>3</sup>	0	24

<sup>1</sup> A total of 3 of the 20 HAV specimens were OraQuick *ADVANCE*® falsely reactive. Two of the 3 specimens were OraQuick *ADVANCE*® non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time. The remaining specimen was reactive at both read times.

<sup>2</sup> One of the specimens was OraQuick *ADVANCE*® non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time.

<sup>3</sup> The OraQuick *ADVANCE*® assay maximum read time for these specimens was 40 minutes. Based upon specimen storage for 5 days at 2-30°C.

As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). None of these disease states, medical conditions or other factors interfered with test specificity. In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test specificity.

## REPRODUCIBILITY

The reproducibility of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was tested at 3 sites using 3 lots of the device on 3 different days with 9 operators (3 per site). A blind-coded panel was tested that consisted of 5 contrived blood specimens (4 antibody-positive and 1 antibody-negative). Test results were recorded at 20-25 minutes and at 55-60 minutes. A total of 405 tests were performed (135/site), with a total of 81 tests per panel member. The overall reproducibility of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was 405/405 = 100%. Concordance between the specified assay read time limits was 99.8% (404/405); a single HIV-1 low positive panel member that was non-reactive at the 20-25 minute read time was reactive at the 55-60 minute read time.

## RESULTS OF UNTRAINED USER STUDY

An "Untrained User" study was conducted in which participants were given only the test instructions and asked to perform testing of a blinded panel comprised of 6 randomized specimens of three different levels (Negative, Low Positive and High Positive OraQuick *ADVANCE*® test reactivity) consisting of human plasma. The participants were not given any training on the use of the test or the interpretation of the test results, nor were they allowed to observe the performance of the Kit Controls by the Study Coordinator. The study protocol stipulated that professionally trained medical laboratory personnel or persons with prior experience using the OraQuick *ADVANCE*® device were excluded from participation. A total of 100 participants were enrolled from a total of four sites, representing a diverse demographic (educational, ethnic, age, gender, etc.) population.

The rate of correct results for the overall study was 98.6% (592/600). Refer to the table below for a summary of the performance relative to the specimen type. The eight incorrect results were attributed to six participants. Of these six participants, four obtained 5 out of 6 correct results, and two participants obtained 4 out of 6 correct results.











Untrained Users Rate of Correct Test Results			
Negative	Low Positive	High Positive	Total
98.5% (197/200) 95% C.I. (95.7% - 99.7%)	98.0% (196/200) 95% C.I. (95.0% - 99.5%)	99.5% (199/200) 95% C.I. (97.3% - 99.9%)	98.6% (592/600) 95% C.I. (97.4% - 99.4%)

There were 1.7% (10/600) Invalid results reported, with 5 of the 10 Invalid results attributed to one participant. All tests were successfully repeated, with 8/10 of the repeat test results interpreted correctly. The 2 incorrect repeat results were attributed to one participant. While most participants were able to obtain valid results with the first attempt, one of the 100 participants experienced five Invalid test results out of six tests performed. Operator error was observed in some cases to be attributed to specimen vial mix-ups. These findings support the need for training of non-laboratory personnel in the handling of multiple samples in a laboratory setting where specimens are tested in batch mode. As part of the Untrained User study, a Participant Feedback Questionnaire was completed. All participants rated the test as 'easy to use' and felt 'able to perform the test correctly'.

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## EXPLANATION OF SYMBOLS

 Batch Code	 <i>In Vitro</i> Diagnostic Medical Device
 Catalog Number	 Manufacturer
 Caution, Consult Accompanying Documents	 Temperature Limitation
 HIV Negative Control	 Use By
 HIV-1 Positive Control	 HIV-2 Positive Control

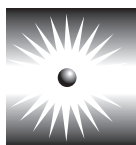
Manufactured by



**OraSure Technologies, Inc.**

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Item #3001-1215 rev. 05/11



**OraSure Technologies, Inc.**

## **Prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® Carta al cliente**

Estimado cliente:

Le agradecemos que haya decidido usar la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. La venta, distribución y empleo de este producto están sujetos a las restricciones que se describen en el instructivo del producto. Al comprar este dispositivo, se entiende que lo hace como representante de un laboratorio clínico y acepta observar y hacer observar por consignatarios en su caso, las restricciones e instrucciones de uso, venta, distribución y empleo del dispositivo/producto.

1. La venta de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® está destinada a laboratorios clínicos
  - que tengan un programa de control de calidad adecuado, que incluya actividades sistemáticas planificadas que permitan asegurar el pleno cumplimiento de los requisitos de calidad<sup>1-3</sup>; y
  - donde se asegura que los operadores recibirán y utilizarán los materiales de capacitación provistos.
2. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® ha sido aprobada para ser utilizada únicamente por un representante de un laboratorio clínico.
3. Los sujetos de prueba deberán recibir el folleto "Información para el paciente" y recibir asesoramiento antes de la obtención de la muestra y asesoramiento adecuado cuando se proporcionen los resultados de la prueba.
4. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® no ha sido aprobada para ser utilizada para fines de detección en donantes de sangre o tejido.

El instructivo de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® contiene advertencias y precauciones, restricciones sobre la venta, distribución y uso del dispositivo e información acerca de cómo funciona, cómo usarla, interpretación de los resultados y limitaciones del procedimiento. El folleto "Información para el paciente" proporciona información para los sujetos sobre las limitaciones de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® y el significado de un resultado de prueba preliminar positivo o negativo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®, así como información general sobre el VIH y el SIDA. Recomendamos que usted se familiarice con esos materiales.

Si tiene preguntas, llame gratis al 1-800-ORASURE (1-800-672-7873) o 1-800-869-3538 y pida hablar con servicio al cliente.

Atentamente,

Servicio al Cliente de OraSure Technologies

### **Bibliografía**

1. CLSI Document GP2-A4, Clinical Laboratory Technical Procedure Manuals
2. CLSI Document GP27-A, Using Proficiency Testing (PT) to Improve the Clinical Laboratory
3. CLSI Document AST2-A, Point-of-Care In Vitro (IVD) Testing

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**Lea este instructivo en su totalidad antes de usar este producto. Siga las instrucciones al pie de la letra al realizar la prueba. De lo contrario, los resultados de la prueba podrían ser inexactos. Antes de realizar las pruebas, todos los operadores DEBEN leer y familiarizarse con las “Precauciones universales para prevenir la transmisión del virus de la inmunodeficiencia humana, el virus de la hepatitis B y otros patógenos transmitidos por la sangre en los entornos de atención de la salud”.<sup>5,9</sup>**

#### **COMPLEJIDAD DE LA PRUEBA: EXENTA**

Cuando es para fluido oral, sangre obtenida por pinchazo del dedo y sangre obtenida por venopunción. La prueba dejará de cumplir con los requisitos de la categoría exenta si el laboratorio hace cualquier modificación al sistema de prueba o a las instrucciones del sistema aprobadas por la FDA.

#### **COMPLEJIDAD DE LA PRUEBA: MODERADA**

Cuando es para plasma.

#### **NOMBRE Y USO PREVISTO**

La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® es un inmunoensayo cualitativo, de un solo uso, para detectar anticuerpos contra el virus de la inmunodeficiencia humana tipo 1 (VIH-1) y tipo 2 (VIH-2) en muestras de fluido oral, sangre obtenida por pinchazo de dedo, sangre obtenida por venopunción y plasma. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® está prevista para ser utilizada como una prueba realizada en el lugar donde se presta atención médica al paciente para facilitar el diagnóstico de infección por el VIH-1 y VIH-2. Esta prueba es adecuada para usar en algoritmos de pruebas múltiples diseñados para validación estadística de los resultados de prueba rápida de VIH. Cuando se disponga de múltiples pruebas rápidas de VIH, esta prueba se deberá usar en los algoritmos de pruebas múltiples apropiados.

#### **RESTRICCIONES**

- **La venta de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® está destinada a laboratorios clínicos**
  - que tengan un programa de control de calidad adecuado, que incluya actividades sistemáticas planificadas que permitan asegurar el pleno cumplimiento de los requisitos de calidad; y
  - donde se asegura que los operadores recibirán y utilizarán los materiales de capacitación provistos.
- **La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® ha sido aprobada para ser utilizada únicamente por un representante de un laboratorio clínico.**
- **Los sujetos de prueba deberán recibir el folleto “Información para el paciente” antes de la obtención de la muestra e información apropiada cuando se proporcionen los resultados de la prueba.**
- **La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® no ha sido aprobada para ser utilizada para fines de detección en donantes de sangre o tejido.**

#### **RESUMEN Y EXPLICACIÓN DE LA PRUEBA**

Se cree que el síndrome de la inmunodeficiencia adquirida (SIDA), el complejo relacionado con el SIDA (CRS) y pre-SIDA son causados por el virus de la inmunodeficiencia humana (VIH). El primer virus relacionado con el SIDA, el VIH-1 (conocido también como el HTLV-III, LAV-1 y ARV) ha sido aislado a partir de pacientes con SIDA y de personas sanas que corren alto riesgo de contraer SIDA.<sup>1,2</sup> El análisis genético de aislados del VIH-1 ha documentado la existencia de subtipos. Hasta la fecha, se han identificado en todo el mundo ocho subtipos del VIH-1 (A hasta H), designados como el grupo M, además de los altamente divergentes aislados del VIH-1 provenientes de pacientes con SIDA de Camerún, designados como el grupo O.<sup>3</sup> Un segundo tipo de retrovirus de la inmunodeficiencia humana patogénica, designado VIH-2 (anteriormente LAV-2) ha sido aislado a partir de pacientes con SIDA en África Occidental. Se ha demostrado que el VIH-2 posee un número de secuencias conservadas compartidas con el VIH-1, pero la reactividad serológica cruzada entre el VIH-1 y el VIH-2 ha demostrado ser muy variable entre una y otra muestra.

Se sabe que el VIH se transmite por contacto sexual, por exposición a la sangre (incluido el uso compartido de agujas y jeringas contaminadas) o por medio de productos de la sangre contaminados; también puede ser transmitido por una madre infectada a su feto durante el periodo prenatal. Los individuos infectados con el VIH producen anticuerpos contra las proteínas víricas del VIH. Hacer una prueba para detectar la presencia de anticuerpos anti VIH en líquidos corporales (p. ej., sangre, líquido de la boca y orina) es un método preciso para diagnosticar la infección por VIH. Sin embargo, se deben considerar las implicaciones de la seropositividad en el contexto clínico. Por ejemplo, en neonatos, la presencia de anticuerpos anti VIH indica exposición al VIH, pero no necesariamente infección por el VIH, debido a la adquisición de los anticuerpos maternos que pueden persistir hasta 18 meses. Por otra parte, la ausencia de anticuerpos anti VIH no se puede considerar como prueba absoluta de que un individuo no está infectado con el VIH o que es incapaz de transmitir el virus. La respuesta de los anticuerpos a una exposición reciente puede tardar meses en llegar a niveles detectables. El VIH ha sido aislado en individuos asintomáticos, seronegativos, supuestamente antes de la seroconversión posterior a la exposición.

El algoritmo de laboratorio típico para detectar el VIH que se utiliza en Estados Unidos consiste en una prueba de detección con un inmunoensayo enzimático (EIA) y confirmación de EIAs repetidamente reactivos usando el método Western. Los resultados típicamente se reportan desde 48 horas hasta 2 semanas después, por lo cual estos análisis de detección y pruebas suplementarias estándar no son adecuados para el diagnóstico rápido del VIH. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® se lleva a cabo en el lugar donde se presta atención médica al paciente para facilitar el diagnóstico de infección por el VIH-1 y VIH-2.

El empleo de la prueba rápida de detección del VIH incrementa el número de personas infectadas con el VIH que se pueden diagnosticar. Los Centros para el Control y Prevención de Enfermedades (Centers for Disease Control and Prevention, CDC) estiman que casi una tercera parte de las personas que se cree están infectadas con el VIH en Estados Unidos (900,000) no saben su estado con respecto al VIH. Como resultado, no pueden aprovechar las ventajas de la intervención temprana con terapia antiviral eficaz. La prueba rápida de detección del VIH resuelve este problema proporcionando resultados durante la consulta inicial y facilitando consejos inmediatos. Además, en el caso de las mujeres embarazadas que no saben si tienen el VIH en el momento del parto, la prueba rápida del VIH hace posible comenzar la terapia en estas madres durante el trabajo de parto y en sus hijos posparto, lo cual reduce considerablemente la posibilidad de que los lactantes sean infectados por el VIH. Asimismo, la prueba rápida de VIH es instrumental en la decisión de iniciar el tratamiento del trabajador sanitario tras la exposición accidental a los líquidos corporales de un individuo infectado. En EE.UU. se estima que cada año ocurren entre 600,000 y 1,000,000 de lesiones por pinchazo de aguja. Las decisiones críticas sobre el tratamiento dependen de la disponibilidad de los resultados de una prueba rápida de VIH que sean exactos.

## PRINCIPIOS BIOLÓGICOS DE LA PRUEBA

La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® es un inmunoensayo que se realiza manualmente, se lee visualmente y toma 20 minutos, para la detección cualitativa de anticuerpos anti VIH-1 y VIH-2 en fluido oral humano, sangre obtenida por medio de un pinchazo del dedo o por venopunción y plasma. La prueba rápida para detección de anticuerpos OraQuick *ADVANCE*® consiste en un dispositivo de prueba de un solo uso y un frasco de un solo uso que contiene una cantidad predeterminada de solución reveladora amortiguada. Cada componente viene sellado en compartimientos separados de una sola bolsa. La prueba rápida para detección de anticuerpos OraQuick *ADVANCE*® utiliza un procedimiento exclusivo de inmunoensayo de flujo lateral. En el alojamiento de plástico del dispositivo hay una tira de prueba que consiste en varios materiales que facilitan la matriz para la inmunocromatografía de la muestra y la plataforma para indicar los resultados.

La tira de la prueba del ensayo, la cual se puede ver a través de la ventanilla de resultados del dispositivo, contiene péptidos sintéticos que representan la región del sobre VIH y un control de procedimiento de IgG antihumano de cabra inmovilizado sobre una membrana de nitrocelulosa en la zona de prueba (T) y en la zona de control (C), respectivamente.

Se obtiene una muestra de fluido oral utilizando la paleta del dispositivo de prueba, lo cual va seguido de la inserción del dispositivo de prueba en el frasco de solución reveladora. Se obtiene una muestra de sangre por medio de pinchazo del dedo o venopunción o una muestra de plasma, la cual se transfiere al frasco de solución reveladora, lo cual va seguido de la inserción del dispositivo de prueba. La solución reveladora facilita el flujo de la muestra al dispositivo y a la tira de prueba. A medida que la muestra diluida fluye a través del dispositivo, rehidrata el reactivo colorimétrico dorado de proteína A que se encuentra en el dispositivo. A medida que la muestra continúa subiendo a través de la tira, llega a la zona T. Si la muestra contiene anticuerpos que reaccionan con los antígenos inmovilizados sobre la membrana de nitrocelulosa, aparece una línea de color rojo-púrpura, lo cual indica cualitativamente la presencia de anticuerpos anti VIH-1 y/o anti VIH-2 en la muestra. La intensidad del color de la línea no es directamente proporcional a la cantidad de anticuerpos que hay en la muestra.

Más arriba de la tira de prueba, la muestra llegará a la zona C. Este control de procedimiento incorporado sirve para demostrar que se añadió una muestra al frasco y que el líquido subió correctamente a través del dispositivo de prueba. Aparecerá una línea de color rojo-púrpura en la zona C cuando se realicen todas las pruebas válidas, independientemente de que la muestra sea seropositiva o seronegativa frente a anticuerpos anti VIH-1 y/o anti VIH-2 (consulte *Resultado de la prueba e Interpretación del resultado de la prueba* en la siguiente sección).

Los resultados de la prueba se interpretan después de 20 minutos, pero antes de transcurridos 40 minutos después de haber introducido el dispositivo de prueba en la solución reveladora que contiene la muestra para la prueba. No se requiere ningún pipetado de precisión, predilución ni instrumentos especializados para llevar a cabo la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

## MATERIALES SUMINISTRADOS

Los juegos de materiales de prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® se ofrecen en las siguientes configuraciones:

Tamaño del juego de materiales	100 unid.	25 unid.
Bolsas divididas, cada una con: Dispositivo para prueba (1) Paquete de absorbente (1) Frasco de solución reveladora (1) (cada frasco contiene 1 ml de una solución salina amortiguada con fosfato que contiene polímeros y un agente antimicrobiano)	100	25
Soportes para prueba reutilizables	10	5
Aros para colección de muestras	100	25
Folleto de información para el paciente	100	25
Instructivo	1	1
Carta al cliente	1	1



## MATERIALES REQUERIDOS QUE SE VENDEN COMO UN ACCESORIO AL JUEGO DE MATERIALES

Controles para el juego de materiales de prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®

El paquete contiene control positivo VIH-1 (1 frasco, tapa negra, 0.2 ml), control positivo VIH-2 (1 frasco, tapa roja, 0.2 ml) y control negativo (1 frasco, tapa blanca, 0.2 ml) y un instructivo.

## MATERIALES NECESARIOS NO SUMINISTRADOS

Cronómetro o reloj capaz de medir 20 a 40 minutos

Manto protector limpio, desechable, absorbente sobre el área de trabajo

Envase para desechar peligros biológicos

**Otros artículos que se requieren para la obtención de muestras de sangre por pinchazo de dedo, sangre por venopunción y muestras de plasma:**

Toallita antiséptica

Lanceta estéril para obtener una muestra de sangre por pinchazo o los materiales requeridos para obtener una muestra de sangre por venopunción

Gasas estériles

Guantes desechables de látex, vinilo o nitrilo (opcionales para la prueba de fluido oral)

Centrifugadora para procesar la muestra de plasma

## ADVERTENCIAS

### Para diagnóstico *in vitro*

1. Lea el instructivo en su totalidad antes de usar este producto. Siga las instrucciones al pie de la letra. De lo contrario, los resultados de la prueba podrían ser inexactos.
2. Antes de realizar la prueba, todos los operadores DEBEN leer y familiarizarse con las "Precauciones universales para prevenir la transmisión del virus de la inmunodeficiencia humana, el virus de la hepatitis B y otros patógenos transmitidos por la sangre en los entornos de atención de la salud".<sup>5,9</sup>
3. La FDA ha aprobado este juego para ser utilizado únicamente con muestras de fluido oral, de sangre obtenida por pinchazo del dedo, de sangre obtenida por venopunción y de plasma. El empleo de este juego para prueba con tipos de muestras que no sean los aprobados específicamente para usar con este dispositivo podría producir resultados inexactos.
4. Esta prueba se debe llevar a cabo en temperaturas dentro del margen de (15 °C - 37 °C, 59 °F - 99 °F). Si se almacena en refrigeración, asegúrese de permitir que la bolsa dividida alcance la temperatura de operación (15 °C - 37 °C, 59 °F - 99 °F) antes de llevar a cabo la prueba.
5. Si el juego de materiales de prueba se almacena a temperaturas fuera de ese margen (2 °C - 27 °C, 35 °F - 80 °F), o si se utiliza fuera de la temperatura de trabajo (15 °C - 37 °C, 59 °F - 99 °F), utilice los controles para garantizar el rendimiento de la prueba.
6. Los individuos infectados con el VIH-1 y/o VIH-2 que estén bajo tratamiento con terapia antirretrovírica (HAART) podrían producir resultados negativos falsos.

## PRECAUCIONES

### Precauciones de seguridad

1. Maneje todas las muestras de sangre y los materiales que entren en contacto con las muestras de sangre como si fuesen capaces de transmitir agentes infecciosos.
2. No beba, coma ni fume en áreas donde se están manejando muestras ni donde se están llevando a cabo pruebas.
3. Use guantes desechables cuando maneje muestras de sangre y cuando haga pruebas con muestras de sangre. Cámbiese los guantes y lávese las manos muy bien después de llevar a cabo cada prueba. Elimine los guantes en un envase para peligros biológicos después de usarlos.
4. El fluido oral no se considera potencialmente infeccioso a menos que contenga sangre.<sup>8</sup> El empleo de guantes es opcional si la prueba es con fluido oral. El personal que administre las pruebas que tenga cortadas o raspadas en la piel o que padezca dermatitis deberá usar guantes cuando lleve a cabo pruebas con fluido oral. Lávese las manos muy bien después de llevar a cabo cada prueba con fluido oral y si entra en contacto con fluido oral.
5. Elimine todas las muestras de prueba y los materiales utilizados en las pruebas en un envase para peligros biológicos. Las lancetas y los materiales para la venopunción se deben colocar en un recipiente resistente a las pinchaduras antes de ser eliminados. El método recomendado para eliminar los peligros biológicos es esterilizar en autoclave por 1 hora como mínimo a 121 °C. Los materiales desechables se pueden incinerar. Los desperdicios líquidos se pueden mezclar con desinfectantes químicos apropiados. Se recomienda una solución recién preparada de blanqueador al 10% (solución de hipoclorito de sodio al 0.5%). Conceda 60 minutos para la descontaminación eficaz. **NOTA: No someta a autoclave ninguna solución que contenga blanqueador.**
6. Limpie todo derrame completamente con una solución de blanqueador al 10% o algún otro desinfectante apropiado.<sup>4</sup> Las soluciones de blanqueador se deben preparar frescas todos los días.
7. Para obtener información adicional sobre la seguridad biológica, consulte "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings"<sup>5,9</sup> y "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis".<sup>8</sup>

### Precauciones en la manipulación

1. Use todos los aros para obtención de muestras, los dispositivos para prueba y los frascos de solución reveladora una sola vez y elimínelos adecuadamente (consulte Precauciones de seguridad). **No reutilice ninguno de esos componentes para la prueba.**
2. No use la prueba después de la fecha de vencimiento impresa en la bolsa dividida. Siempre verifique la fecha de vencimiento antes de hacer la prueba.
3. No intercambie dispositivos de prueba y frascos de solución reveladora de diferentes números de lote.
4. Evite la contaminación microbiana y proceda con cautela en la manipulación de los componentes del juego.
5. Para asegurar que los resultados sean precisos, el dispositivo de prueba se debe introducir en el frasco de solución reveladora en un plazo de 60 minutos de haber introducido la muestra de sangre obtenida por pinchazo del dedo, por venopunción o la muestra de plasma.
6. Cuando obtenga muestras de fluido oral, el dispositivo de prueba se debe introducir en el frasco de solución reveladora en un plazo de 30 minutos de haber obtenido la muestra. Si no se introducirá el dispositivo de prueba que contiene la muestra de fluido oral en el frasco de solución reveladora antes de transcurridos 10 minutos de la obtención de la muestra, éste se debe almacenar sobre una superficie plana o guardar en la bolsa dividida después de retirar el paquetito de absorbente de la bolsa dividida. Si el lapso será de 10 a 30 minutos, guarde el dispositivo de prueba que contiene la muestra bucal en la bolsa dividida, pero primero saque el desecante de la bolsa dividida. Coloque la bolsa dividida que contiene el dispositivo de prueba en posición horizontal hasta que introduzca el dispositivo de prueba en el frasco de solución reveladora.
7. Se requiere iluminación adecuada para leer el resultado de la prueba.

### INSTRUCCIONES PARA EL ALMACENAMIENTO

Almacene los controles para el juego de materiales de prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® a una temperatura de 2 °C -27 °C (35 °F -80 °F). No abra la bolsa dividida hasta que esté preparado para llevar a cabo una prueba. Si se almacena en refrigeración, asegúrese de permitir que la bolsa dividida alcance la temperatura de operación (15 °C - 37 °C, 59 °F - 99 °F) antes de abrirla.

### MODO DE EMPLEO

#### PREPARE EL ÁREA DE TRABAJO

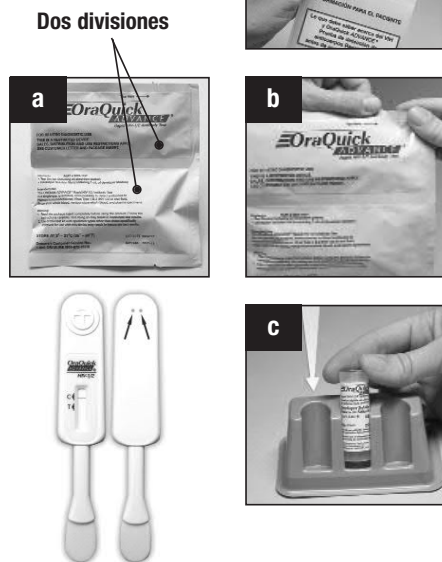
- Reúna los materiales necesarios.
- Deje que el juego de materiales de prueba se aclimate a la temperatura de trabajo (15 °C - 37 °C; 59 °F - 99 °F) antes de usarlo.
- Consulte la sección *Control de calidad externo* de este instructivo, para determinar cuándo se deben efectuar los controles del juego de materiales.
- Cubra el área de trabajo con un manto limpio, absorbente y desechable.
- Coloque un soporte para pruebas reutilizable OraQuick ADVANCE® (en adelante “soporte”) sobre el manto que cubre el área de trabajo. Use únicamente el soporte suministrado.
- Póngase los guantes desechables según corresponda de conformidad con la sección de *Precauciones de seguridad* de este instructivo.

**Antes de hacer la prueba, entréguele el folleto titulado “Información para el paciente” a la persona a la que le está haciendo la prueba.**

#### PREPARACIÓN GENERAL PARA LA PRUEBA

1. Abra las dos divisiones de la bolsa del OraQuick ADVANCE® (en adelante la “bolsa”) rasgando en las muescas situadas en la parte superior de cada lado de la bolsa (vea las figuras a y b). Para prevenir la contaminación, deje el dispositivo de prueba (en adelante el “dispositivo”) en la bolsa hasta que esté preparado para usarlo.
2. Saque el frasco de solución reveladora (en adelante el “frasco”) de la bolsa. Sujete el frasco firmemente con la mano. Qúitele la tapa al frasco lentamente, moviendo la tapa hacia delante y hacia atrás a la vez que tira de ella. Coloque la tapa sobre el manto del área de trabajo.
3. Coloque el frasco en una de las ranuras del soporte. **NO** lo introduzca a la fuerza por la parte delantera de la ranura, pues podría salpicar. Asegúrese de que el frasco esté hasta el fondo de la ranura del soporte (vea la figura c).

**NOTA: NO cubra los dos orificios situados en la parte posterior del dispositivo con etiquetas ni con otros materiales. De lo contrario, se podría invalidar el resultado.**



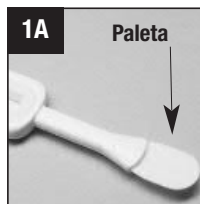
## OBTENCIÓN DE LA MUESTRA Y PROCEDIMIENTO DE PRUEBA

La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® se puede usar para hacer pruebas con muestras de fluido oral, sangre obtenida por pinchazo del dedo, sangre obtenida por venopunción y muestras de plasma. Consulte el procedimiento de prueba específico a continuación.

### PROCEDIMIENTO PARA FLUIDO ORAL

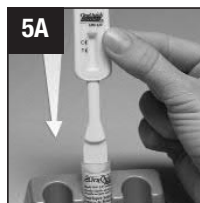
#### PASO 1: OBTENER LA MUESTRA

1. Asegúrese de que el sujeto no haya comido, bebido o usado goma de mascar durante al menos 15 minutos antes de la prueba. Si ha usado algún enjuague bucal, espere 30 minutos como mínimo antes de hacer la prueba.
2. Pídale a la persona a quien le está haciendo la prueba que saque el dispositivo de la bolsa. **NO** permita que la persona toque la paleta (vea la figura 1A). Revise que con el dispositivo se incluya un paquete de absorbente (vea la figura 2A). Si no hay un paquete de absorbente, elimine el dispositivo y obtenga una bolsa nueva para la prueba.
3. Indíquelo a la persona que se coloque la paleta arriba de los dientes, sobre el exterior de la encía. Pídale a la persona que con la paleta se frote suavemente por toda la parte exterior de las encías superior e inferior, una vez (vea las figuras 3A y 4A). **NO** permita que la persona se pase la paleta por el paladar ni la lengua ni el interior de los cachetes. **NOTA:** Se pueden usar ambos lados de la paleta.



#### PASO 2: HACER LA PRUEBA

1. Inserte la paleta del dispositivo completamente en el frasco (vea la figura 5A). Verifique que la paleta toque el fondo del frasco. La ventanilla de resultados del dispositivo debe estar hacia usted (vea la figura 6A).
2. Comience a contar los minutos de la prueba (vea la figura 7A). **NO** retire el dispositivo del frasco mientras está haciendo la prueba. Aparecerá un líquido rosa que subirá a través de la ventanilla de resultados. El líquido rosa desaparecerá gradualmente a medida que se revela la prueba (vea la figura 8A). Lea los resultados después de 20 minutos, pero no más de 40 minutos en un lugar completamente iluminado.
3. Consulte la sección *Resultado de la prueba e Interpretación del resultado de la prueba*.



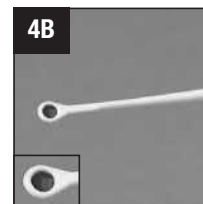
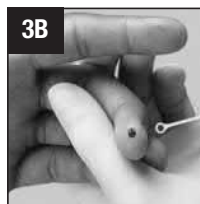
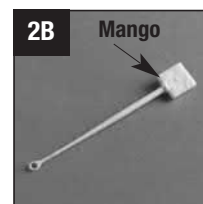
### PROCEDIMIENTO PARA SANGRE OBTENIDA POR PINCHAZO DEL DEDO Y VENOPUNCIÓN

#### PASO 1: OBTENER LA MUESTRA

Las muestras de sangre se pueden obtener por pinchazo del dedo (vea el Paso 1A) o por venopunción (vea el paso 1B).

##### PASO 1A: SANGRE OBTENIDA POR PINCHAZO DEL DEDO

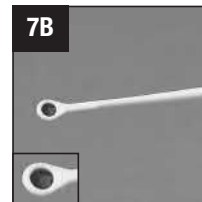
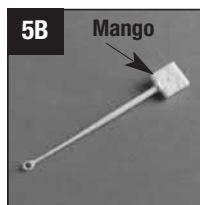
1. Con una toallita antiséptica limpie el dedo de la persona a quien le va a hacer la prueba. Después de limpiar el sitio de la punción en la piel, deje que la zona se seque al aire para que la acción antiséptica del alcohol pueda surtir efecto. Con una lanceta estéril, pinche la piel casi en el centro de la yema del dedo. Voltee el dedo hacia abajo. Aplique un poco de presión junto al lugar de la punción. No apriete el dedo con el fin de hacerlo sangrar (vea la figura 1B). Limpie la primera gota de sangre con una gasa estéril. Deje que se forme otra gota de sangre.
2. Tome un aro para obtención de muestras sin usar, sujetándolo por el extremo grueso o "mango" (vea la figura 2B). Coloque el aro sobre la gota de sangre (vea la figura 3B). Verifique que el aro esté completamente lleno de sangre (vea la figura 4B). **NOTA:** Si deja caer el aro o si éste entra en contacto con alguna superficie, elimínelo en un envase para peligros biológicos. Obtenga un nuevo aro para la muestra.





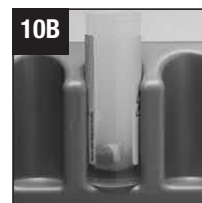
### PASO 1B: SANGRE OBTENIDA POR VENOPUNCIÓN

1. Usando una técnica estándar de flebotomía venosa, obtenga una muestra de sangre con un tubo que contenga cualquiera de los siguientes anticoagulantes: EDTA (tapa lavanda), heparina sódica (tapa verde), citrato de sodio (tapa azul claro). **No se han puesto a prueba otros anticoagulantes y es posible que den resultados incorrectos.** Si no se hace la prueba inmediatamente después de la obtención de la muestra, la sangre se puede almacenar a 2 °C - 30 °C (35 °F - 86°F) hasta 5 días. Antes de hacer la prueba, mezcle el tubo suavemente invirtiéndolo varias veces para asegurar la homogeneización de la muestra.
2. Tome un aro para obtención de muestras sin usar, sujetándolo por el extremo grueso o "mango" (vea la figura 5B). Coloque el aro en el tubo de sangre (vea la figura 6B). Verifique que el aro esté completamente lleno de sangre (vea la figura 7B). NOTA: Si deja caer el aro o si éste entra en contacto con alguna superficie, elimínelo en un envase para peligros biológicos. Obtenga un nuevo aro para la muestra.



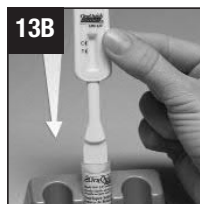
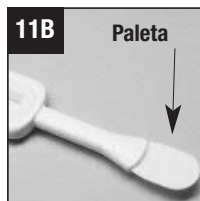
### PASO 2: MEZCLAR

1. Inmediatamente introduzca el aro con sangre completamente en el frasco (vea la figura 8B). Use el aro para mezclar la muestra de sangre dentro de la solución reveladora (en adelante la "solución") (vea la figura 9B). Retire el aro usado de la solución. Elimine el aro en un envase para peligros biológicos.
2. Revise la solución para asegurarse de que se ve de color rosa. Eso significa que la sangre está correctamente mezclada con la solución (vea la figura 10B). Si la solución no se ve de color rosa, deseche todos los materiales de la prueba en un envase para peligros biológicos. Comience la prueba otra vez. Use una bolsa nueva y una nueva muestra de sangre.



### PASO 3: HACER LA PRUEBA

1. Retire el dispositivo de la bolsa. **NO** toque la paleta (vea la figura 11B). Revise que con el dispositivo se incluya un paquete de absorbente (vea la figura 12B). Si no hay un paquete de absorbente, elimine el dispositivo y obtenga una bolsa nueva para la prueba.
2. Introduzca la paleta del dispositivo completamente en el frasco que contiene la muestra de sangre (vea la figura 13B). Verifique que la paleta toque el fondo del frasco. La ventanilla de resultados del dispositivo debe estar hacia usted (vea la figura 14B).
3. Comience a contar los minutos de la prueba (vea la figura 15B). **NO** retire el dispositivo del frasco mientras está haciendo la prueba. Aparecerá un líquido rosa que subirá a través de la ventanilla de resultados. El líquido rosa desaparecerá gradualmente a medida que se revela la prueba (vea la figura 16B). Lea los resultados después de 20 minutos, pero antes de que transcurran 40 minutos, en un lugar completamente iluminado.
4. Consulte la sección *Resultado de la prueba e Interpretación del resultado de la prueba* en este instructivo.

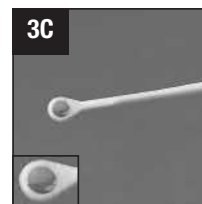
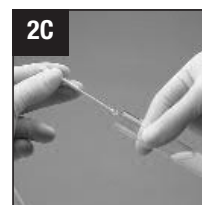
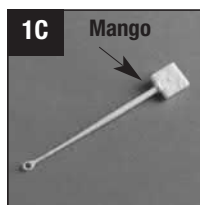


## PROCEDIMIENTO CON PLASMA

**NOTA:** Las pruebas con plasma sólo se pueden hacer en laboratorios certificados para realizar pruebas de complejidad moderada.

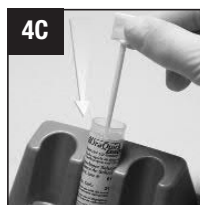
### PASO 1: OBTENER LA MUESTRA

1. Usando una técnica estándar de flebotomía venosa, obtenga una muestra de sangre usando un tubo que contenga el anticoagulante EDTA (tapa lavanda). **No se han puesto a prueba otros coagulantes y es posible que den resultados incorrectos.** Si no se hace la prueba inmediatamente después de obtener la muestra, ésta se podrá almacenar como sangre hasta 5 días a 2 °C - 30 °C (35 °F - 86 °F) o como plasma hasta 7 días a 2 °C - 8 °C (35 °F - 46 °F).
2. Centrifuge el tubo de sangre (1000 - 1300 x *g*, durante aproximadamente 5 minutos, no se requiere refrigeración) para separar las células del plasma. Destape lentamente el tubo, moviendo el tapón hacia usted, para que los vapores salgan por el lado opuesto.
3. Tome un aro para obtención de muestras, sujetándolo por el extremo grueso o "mango" (vea la figura 1C). Coloque el aro en el tubo de plasma (vea la figura 2C). Verifique que el aro esté completamente lleno de plasma (vea la figura 3C). NOTA: Si deja caer el aro o si éste entra en contacto con alguna superficie, elimínelo en un envase para peligros biológicos. Obtenga un nuevo aro para la muestra de plasma.



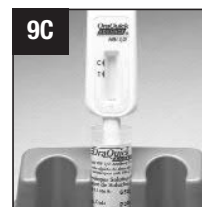
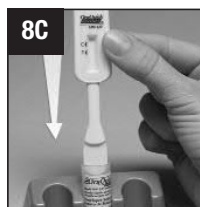
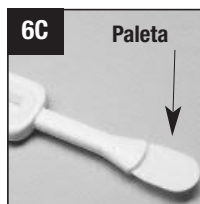
### PASO 2: MEZCLAR

1. Inmediatamente introduzca el aro con plasma completamente en el frasco (vea la figura 4C). Use el aro para mezclar la muestra de plasma dentro de la solución reveladora (en adelante la "solución") (vea la figura 5C). Retire el aro usado de la solución. Elimine el aro en un envase para peligros biológicos.



### PASO 3: HACER LA PRUEBA

1. Retire el dispositivo de la bolsa. **NO** toque la paleta (vea la figura 6C). Revise que con el dispositivo se incluya un paquete de absorbente (vea la figura 7C). Si no hay un paquete de absorbente, elimine el dispositivo y obtenga una bolsa nueva para la prueba.
2. Introduzca la paleta del dispositivo completamente en el frasco que contiene la muestra de sangre (vea la figura 8C). Verifique que la paleta toque el fondo del frasco. La ventanilla de resultados del dispositivo debe estar hacia usted (vea la figura 9C).
3. Comience a contar los minutos de la prueba (vea la figura 10C). **NO** retire el dispositivo del frasco mientras está haciendo la prueba. Aparecerá un líquido rosa que subirá a través de la ventanilla de resultados. El líquido rosa desaparecerá gradualmente a medida que se revela la prueba (vea la figura 11C). Lea los resultados después de 20 minutos, pero no más de 40 minutos en un lugar completamente iluminado.
4. Consulte la sección *Resultado de la prueba e Interpretación del resultado de la prueba* en este instructivo.



### LIMPIEZA GENERAL DESPUÉS DE LA PRUEBA

1. Elimine los materiales utilizados en la prueba en un envase para peligros biológicos.
2. Cuando use guantes, cámbieselos entre cada prueba para evitar la contaminación. Elimine los guantes usados en un envase para peligros biológicos.
3. Use una solución recién preparada de blanqueador al 10% para limpiar cualquier derrame.

## CONTROL DE CALIDAD

### Características de control incorporadas

La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® posee un control de procedimiento incorporado que demuestra la validez del ensayo. Aparece una línea rojo-púrpura en el área de control ("C") de la ventanilla de resultados que indica que se añadió una muestra y que el líquido ascendió correctamente a través del dispositivo de prueba. La línea de control aparecerá en todas las pruebas válidas, independientemente de que la muestra sea reactiva o no reactiva. (Consulte la sección *Resultado de la prueba e Interpretación del resultado de la prueba* a continuación.)

### Control de calidad externo

Los controles para el juego de materiales de prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® se venden por separado y deben utilizarse únicamente con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Los controles se formulan y elaboran específicamente para asegurar el rendimiento de la prueba y se usan para verificar la habilidad del usuario para llevar a cabo la prueba e interpretar los resultados correctamente. Los controles VIH-1 y VIH-2 positivo producen un resultado de prueba reactivo y han sido elaborados para producir una muy tenue línea de prueba ("T"). El control negativo produce un resultado de prueba no reactivo. (Consulte la sección *Resultado de la prueba e Interpretación del resultado de la prueba* a continuación.) El empleo de reactivos de control para pruebas de otros fabricantes podrían no producir los resultados requeridos y por lo tanto no cumplirían con las disposiciones de un programa de control de calidad adecuado para la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

Utilice los controles para el juego de materiales en las siguientes circunstancias:

- Con cada operador nuevo antes de realizar pruebas en muestras de pacientes,
- Cuando abra un lote nuevo de pruebas,
- Cuando se reciba un nuevo envío de juegos de prueba,
- Si la temperatura del área del juego de materiales de prueba se encuentra fuera del margen de 2 °C - 27 °C (35 °F - 80 °F),
- Si la temperatura del área de pruebas se encuentra fuera del margen de 15 °C - 37 °C (59 °F - 99 °F),
- A intervalos periódicos según lo dicten las centros del usuario.

Consulte el instructivo de los controles de prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® para las instrucciones de empleo de estos reactivos. Recae sobre cada laboratorio que utilice la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® la obligación de establecer un programa de control de calidad adecuado para asegurar el rendimiento del dispositivo en el lugar y situaciones de uso específicos. Comuníquese con el departamento de atención al cliente de OraSure Technologies si los reactivos del control para el juego de materiales no producen los resultados esperados.

## RESULTADO DE LA PRUEBA E INTERPRETACIÓN DEL RESULTADO DE LA PRUEBA

Mire la ventanilla de resultados del dispositivo de prueba.

### NO REACTIVO

En el diagrama de la derecha se muestra un ejemplo de un resultado de prueba **No Reactivo**.

Una prueba es no reactiva si:

aparece una línea de color rojo-púrpura junto al triángulo que dice "C" **y** NO aparece ninguna línea junto al triángulo que dice "T".

Un resultado **No Reactivo** significa que no se detectaron anticuerpos anti VIH-1 y VIH-2 en la muestra. El resultado de la prueba se interpreta como **NEGATIVO ante anticuerpos contra VIH-1 y VIH-2**. Siga las pautas del CDC para informar al paciente del resultado y su interpretación.<sup>6,7</sup>

### REACTIVO

En el diagrama de la derecha se muestra un ejemplo de un resultado de prueba **Reactivo**.

Una prueba es **Reactiva** si:

aparece una línea de color rojo-púrpura junto al triángulo que dice "C" **y** aparece una línea rojo-púrpura junto al triángulo que dice "T". Una de esas líneas puede ser más oscura que la otra.

**NOTA:** El resultado de la prueba es **Reactivo** si aparece **cualquier** línea rojo-púrpura junto al triángulo que dice "T" **y** junto al triángulo "C", sin importar si son muy tenues.

Un resultado **Reactivo** significa que se detectaron anticuerpos anti VIH-1 y/o VIH-2 en la muestra. El resultado de la prueba se interpreta como **PRELIMINAR POSITIVO ante anticuerpos anti VIH-1 y/o VIH-2**. Siga las pautas del CDC para informar al paciente del resultado y su interpretación.<sup>6,7</sup>





## INVÁLIDO

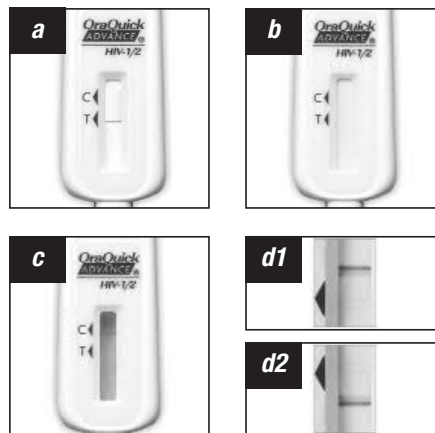
En el diagrama de la derecha se muestra un ejemplo de un resultado de prueba **Inválido**.

Una prueba es **Inválida** si ocurre cualquiera de las siguientes situaciones:

- **NO** aparece ninguna línea rojo-púrpura junto al triángulo que dice "C" (vea la figura a y b) o
- después de 20 minutos el fondo de la ventana de resultados se vuelve rojizo y dificulta la lectura de los resultados (vea la figura c), o
- si alguna de las líneas NO está dentro de las áreas del triángulo "C" o "T" (vea las figuras d1 y d2).

Un resultado de prueba **Inválido** significa que surgió algún problema al ejecutar la prueba, bien sea relacionado con la muestra o con el dispositivo de prueba. Los resultados **Inválidos** no se pueden interpretar.

**Repita la prueba con una bolsa dividida nueva y una nueva muestra de fluido oral, sangre de pinchazo de dedo o venopunción, o una muestra de plasma. Comuníquese con el departamento de atención al cliente de OraSure Technologies si no puede obtener un resultado de prueba válido después de repetir la prueba.**



## LIMITACIONES DE LA PRUEBA

1. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® se debe usar de conformidad con las instrucciones del instructivo para obtener un resultado preciso.
2. La lectura de los resultados de prueba antes de 20 minutos o después de 40 minutos podría producir resultados erróneos.
3. La FDA ha aprobado este juego de materiales para ser utilizado únicamente con muestras de fluido oral, de sangre obtenida por pinchazo del dedo, de sangre obtenida por venopunción y de plasma. El empleo de otros tipos de muestras, la prueba con muestras de sangre obtenidas por venopunción conservadas en tubos que contienen anticoagulantes que no sean EDTA, heparina sódica o citrato de sodio o la prueba con muestras de plasma conservadas en un tubo con anticoagulante que no sea EDTA podrían no producir resultados precisos.
4. Los individuos infectados con el VIH-1 o VIH-2 que estén bajo tratamiento con terapia antirretrovírica (HAART) podrían producir resultados negativos falsos.
5. No se han obtenido datos clínicos que demuestren el rendimiento de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en personas menores de 12 años de edad.
6. Un resultado reactivo obtenido por medio de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® sugiere la presencia de anticuerpos anti VIH-1 y/o anti VIH-2 en la muestra. La prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® está prevista para facilitar el diagnóstico de infección por el VIH-1 y/o VIH-2. El SIDA y las afecciones médicas relacionadas con el SIDA son síndromes clínicos y su diagnóstico sólo puede establecerse clínicamente.
7. En el caso de un resultado reactivo, la intensidad de la línea de prueba no guarda necesariamente una correlación directa con la cantidad de anticuerpo en la muestra.
8. Un resultado no reactivo no elimina la posibilidad de exposición al VIH o infección por el VIH. La respuesta de los anticuerpos a una exposición reciente puede tardar meses en llegar a niveles detectables.
9. La persona que tenga anticuerpos contra el VIH-1 o VIH-2 se considerará infectada con el virus, salvo que en el caso de una persona que haya participado en un estudio de vacuna contra el VIH su organismo podría haber creado anticuerpos a la vacuna y podría estar o no estar infectada con el VIH. Es necesario realizar una correlación clínica con asesoría apropiada, evaluación médica y posibles análisis adicionales para decidir si el diagnóstico de infección con el VIH es acertado.

## CARACTERÍSTICAS DE RENDIMIENTO

### SENSIBILIDAD

#### DETECCIÓN DE ANTICUERPOS ANTI VIH-1 EN MUESTRAS DE INDIVIDUOS INFECTADOS CON EL VIH-1

##### FLUIDO ORAL

Se llevó a cabo un estudio de sensibilidad en ocho centros de ensayo clínico usando muestras de fluido oral recién obtenido de 767 individuos de quienes se había reportado tenían infección por el VIH-1. De las 767 muestras identificadas como seropositivas por medio de pruebas de confirmación autorizadas, 762 produjeron un resultado reactivo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Los resultados del estudio se muestran en la tabla 1.

Se llevó a cabo un estudio separado en cuatro centros de ensayo clínico usando muestras de fluido oral recién obtenido de 3150 individuos en quienes no se habían llevado a cabo pruebas de detección, procedentes de poblaciones que corren alto riesgo de infección por el VIH-1. Los resultados del estudio también se muestran en la tabla 1. De las 73 muestras identificadas como seropositivas por medio de pruebas de confirmación autorizadas, 72 produjeron un resultado reactivo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

**TABLA 1**  
**Detección de anticuerpos anti VIH-1 en muestras de fluido oral**  
**obtenidas de individuos seropositivos ante el VIH-1**

Grupo de prueba	Total de muestras	OraQuick <i>ADVANCE</i> ® reactivo	EIA autorizado repetidamente	Positivo verdadero <sup>1</sup>
Seropositivo ante VIH-1 confirmado	767	762	764	767
Alto riesgo	3150	72 <sup>2</sup>	74 <sup>3</sup>	73
TOTAL	3917	834	838	840

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western (inmunotransferencia) de VIH-1 autorizado, con confirmación de resultados indeterminados con el método Western por ensayo de inmunofluorescencia (IFA) autorizado.

<sup>2</sup> Ocho muestras adicionales resultaron positivo falso con OraQuick *ADVANCE*® (vea la tabla 7).

<sup>3</sup> Una muestra resultó positivo falso con el EIA, con inmunotransferencia negativa.

Al combinar la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos del estudio de positivos confirmados con la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la sensibilidad de la prueba para detección de anticuerpos OraQuick *ADVANCE*® en estos estudios fue de  $834/840 = 99.3\%$  (95% I.C. = 98.4% - 99.7%).

#### PLASMA

Se llevó a cabo un estudio de sensibilidad en once centros de ensayo clínico usando muestras de plasma conservado en EDTA de 891 individuos de quienes se había reportado tenían infección por el VIH-1. De las 891 muestras identificadas como seropositivas por medio de pruebas de confirmación autorizadas, 887 produjeron un resultado reactivo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Los resultados del estudio se muestran en la tabla 2.

Se llevó a cabo un estudio separado en seis centros de ensayo clínico usando muestras de plasma conservado en EDTA, obtenidas de 533 individuos en quienes no se habían llevado a cabo pruebas de detección, procedentes de poblaciones que corren alto riesgo de infección por el VIH-1. Los resultados del estudio también se muestran en la tabla 2. Todas las 14 muestras identificadas como seropositivas por medio de pruebas de confirmación autorizadas produjeron un resultado reactivo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

**TABLA 2**  
**Detección de anticuerpos anti VIH-1 en muestras de plasma**  
**obtenidas de individuos seropositivos ante el VIH-1**

Grupo de prueba	Total de muestras	OraQuick <i>ADVANCE</i> ® reactivo	EIA autorizado repetidamente	Positivo verdadero <sup>1</sup>
Seropositivo ante VIH-1 confirmado	891	887	891	891
Alto riesgo	533	14 <sup>2</sup>	14	14
TOTAL	1424	901	905	905

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western de VIH-1 autorizado, con confirmación de resultados indeterminados con el método Western por ensayo de radioinmunoprecipitación (RIPA) o IFA autorizado.

<sup>2</sup> Una muestra adicional resultó positivo falso con OraQuick *ADVANCE*® (vea la tabla 8).

Al combinar la cantidad de resultados reactivos OraQuick *ADVANCE*® obtenidos del estudio de positivos confirmados con la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la sensibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en estos estudios fue de  $901/905 = 99.6\%$  (95% I.C. = 98.9% - 99.8%).

#### SANGRE OBTENIDA POR PINCHAZO DEL DEDO

Se llevó a cabo un estudio de sensibilidad en ocho centros de ensayo clínico usando muestras de sangre recién obtenidas por pinchazo de dedo de 481 individuos de quienes se había reportado tenían infección por el VIH-1 y 40 pacientes con SIDA. De las 521 muestras que repetidamente resultaron reactivas usando el EIA autorizado y positivas por el método Western, 519 produjeron un resultado reactivo con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Los resultados del estudio se muestran en la tabla 3.

Se llevó a cabo un estudio separado en siete centros de ensayo clínico usando muestras de sangre recién obtenidas por pinchazo de dedo de individuos en quienes no se había llevado a cabo pruebas de detección, procedentes de poblaciones que corren alto riesgo de infección por el VIH-1. Los resultados del estudio también se muestran en la tabla 3. De las 625 muestras sometidas a la prueba, 20 resultaron repetidamente reactivas usando un EIA autorizado, de las cuales 17 fueron positivas por el método Western. Las mismas 17 muestras produjeron un resultado reactivo usando la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

**TABLA 3**  
**Detección de anticuerpos anti VIH-1 en muestras de sangre obtenida por pinchazo de dedo de pacientes con SIDA e individuos seropositivos ante el VIH-1.**

Grupo de prueba	Total de muestras	OraQuick <i>ADVANCE</i> ® reactivo	EIA autorizado repetidamente	Positivo verdadero <sup>1</sup>
SIDA	40	40	40	40
Positivo ante el VIH-1 confirmado	481	479	481	481
Alto riesgo	625	17	20 <sup>2</sup>	17
TOTAL	1146	536	541	538

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western de VIH-1 autorizado, con confirmación de resultados indeterminados con el método Western por RIPA.

<sup>2</sup> Dos muestras fueron negativas y una indeterminada con el método Western con un RIPA negativo.

Al combinar la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos del estudio de positivos confirmados con la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la sensibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en estos estudios fue de  $536/538 = 99.6\%$  (95% I.C. = 98.5% -99.9%).

#### **Reactividad con muestras de VIH-1 procedentes de diferentes regiones geográficas**

Con el fin de evaluar la sensibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® frente a variantes de diferentes regiones geográficas, se obtuvieron 215 muestras de suero/plasma positivas ante el VIH-1 confirmadas de varios lugares del mundo. De estas 215 muestras, 214 produjeron un resultado reactivo usando la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Una muestra positiva ante VIH-1 confirmada procedente de China produjo un resultado no reactivo con la prueba para detección de anticuerpos OraQuick *ADVANCE*®. Trece muestras adicionales que representaban los subtipos A, B, C, D, F y G y el grupo O del VIH-1 se sometieron a la prueba y resultaron reactivas con OraQuick *ADVANCE*®.

#### **Reactividad con paneles de seroconversión de VIH-1**

Se sometieron a prueba once paneles de seroconversión de VIH-1 en comparación con ensayos EIA anti VIH autorizados. Cada panel consistió en muestras sucesivas de suero/plasma obtenidas de un solo individuo durante la seroconversión. Los once paneles de seroconversión consistieron en 69 muestras. Los resultados del estudio se muestran en la tabla 4. En este estudio, se demostró que la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® es capaz de detectar la seroconversión de manera similar a los EIA disponibles actualmente y autorizados por la FDA.

**TABLA 4**  
**Comparación de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®**  
**y los ensayos EIA anti VIH autorizados usando paneles de seroconversión**

Información de la muestra			Ensayos EIA anti VIH autorizados				
Panel	Día relativo de obtención de la muestra	Prueba OraQuick <i>ADVANCE</i> ®	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
K	1	NR	NR	NR	NR	NR	NR
	7	NR	NR	NR	NR	NR	NR
	9	NR	NR	NR	NR	NR	NR
	14	R	NR	RR	NR	NR	NR
	16	R	NR	RR	NR	NR	NR
	21	R	NR	RR	NR	RR	RR
	23	R	RR	RR	RR	RR	RR
	30	R	RR	RR	RR	RR	RR
	34	R	RR	RR	RR	RR	RR
	37	R	RR	RR	RR	RR	RR
N	1	R	RR	RR	NR	NR	NR
	5	R	RR	RR	NR	RR	NR
	8	R	RR	RR	NR	RR	NR
	26	R	RR	RR	RR	RR	RR
	32	R	RR	RR	RR	RR	RR
Q	1	NR	NR	NR	NR	NR	NR
	54	NR	NR	NR	NR	NR	NR
	58	NR	NR	NR	NR	NR	NR
	61	NR	NR	RR	NR	NR	NR
	66	R	NR	RR	NR	NR	NR
	68	R	RR	RR	NR	NR	NR
	73	R	RR	RR	RR	RR	RR
R (M)	3	NR	NR	RR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	14	R	RR	RR	RR	RR	RR
	16	R	RR	RR	RR	RR	RR
	22	R	RR	RR	RR	RR	RR
S	1	NR	NR	NR	NR	NR	NR
	10	R	RR	RR	NR	NR	NR
	12	R	RR	RR	NR	RR	NR
W	1	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	13	NR	NR	NR	NR	NR	NR
	15	NR	NR	NR	NR	NR	NR
	29	NR	NR	NR	NR	NR	NR
	31	NR	NR	NR	NR	NR	NR
	36	NR	NR	NR	NR	NR	NR
	38	NR	NR	NR	NR	NR	NR
	48	NR	NR	RR	NR	NR	NR
	85	R	RR	RR	RR	RR	RR
	87	R	RR	RR	RR	RR	RR
	146	R	RR	RR	RR	RR	RR
	162	R	RR	RR	RR	RR	RR
AB	1	NR	NR	NR	NR	NR	NR
	29	NR	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	NR	NR
	36	R	RR	RR	NR	NR	RR
	41	R	RR	RR	RR	RR	RR

Información de la muestra			Ensayos EIA anti VIH autorizados				
Panel	Día relativo de obtención de la muestra	Prueba OraQuick <i>ADVANCE</i> ®	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
AC	1	NR	NR	NR	NR	NR	NR
	112	NR	NR	RR	NR	NR	NR
	121	R	RR	RR	RR	RR	RR
	126	R	RR	RR	RR	RR	RR
	131	R	RR	RR	RR	RR	RR
AE	1	NR	NR	NR	NR	NR	NR
	4	NR	NR	NR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	11	NR	RR	RR	NR	RR	NR
AF	1	NR	NR	NR	NR	NR	NR
	3	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	10	NR	NR	NR	NR	NR	NR
	16	NR	NR	NR	NR	NR	NR
	29	R	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	RR	RR
	36	R	RR	RR	RR	RR	RR
AI	1	NR	NR	NR	NR	NR	NR
	8	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	RR	RR

NR = No reactivo; R = Reactivo; RR = Repetidamente reactivo

#### Reactividad con paneles con bajo valor de VIH-1

Se sometieron a prueba dos paneles de anticuerpos anti VIH-1 de bajo valor en comparación con ensayos EIA anti VIH autorizados. Los paneles de anticuerpos de bajo valor consistieron en 30 muestras de suero/plasma. Los resultados del estudio se muestran en la tabla 5. En este estudio, se demostró que la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® es capaz de detectar la anticuerpos anti VIH-1 de manera similar a los EIA disponibles actualmente y autorizados por la FDA.

**TABLA 5**  
**Comparación de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® y los ensayos EIA anti VIH autorizados usando paneles de anticuerpos anti VIH-1 de bajo valor**

Información de la muestra			Ensayos EIA anti VIH autorizados				
Panel	Miembro	Prueba OraQuick <i>ADVANCE</i> ®	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT106	1	R	RR	RR	RR	RR	RR
	2	NR	NR	RR	NR	NR	NR
	3	R	RR	RR	RR	RR	RR
	4	R	RR	RR	RR	RR	RR
	5	R	RR	RR	RR	RR	RR
	6	NR	NR	NR	NR	NR	NR
	7	R	RR	RR	RR	RR	RR
	8	NR	RR	RR	NR	NR	NR
	9	R	RR	RR	RR	RR	RR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	NR	RR
	13	R	RR	RR	RR	RR	RR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

Información de la muestra		Ensayos EIA anti VIH autorizados					
Panel	Miembro	Prueba OraQuick ADVANCE®	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT107	1	NR	NR	RR	RR	NR	NR
	2	R	NR	RR	RR	RR	NR
	3	R	NR	RR	NR	NR	NR
	4	R	RR	RR	RR	RR	NR
	5	NR	NR	NR	NR	NR	NR
	6	R	RR	RR	RR	RR	NR
	7	NR	NR	RR	RR	NR	NR
	8	NR	NR	RR	NR	RR	NR
	9	NR	NR	RR	NR	NR	NR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	RR	RR	RR
	12	NR	NR	RR	NR	NR	NR
	13	NR	NR	RR	RR	NR	NR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

NR = No reactivo; R = Reactivo; RR = Repetidamente reactivo

#### SUSTANCIAS QUE INTERFIEREN Y AFECCIONES MÉDICAS NO RELACIONADAS

Con el fin de evaluar el impacto de las afecciones médicas no relacionadas o la interferencia de sustancias con la sensibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®, se adulteraron con una muestra positiva ante el VIH-1 200 muestras de suero/plasma de una variedad de afecciones médicas no relacionadas con la infección por el VIH-1 y 125 muestras que contenían sustancias interferentes para producir un nivel de reactividad en el margen positivo bajo (ver la lista de afecciones médicas y sustancias interferentes en la tabla 10 a continuación). Todas las muestras adulteradas produjeron resultados reactivos.

Además, se llevó a cabo un estudio para evaluar el efecto potencial de los anticoagulantes sobre la sensibilidad del ensayo. Sangre obtenida por venopunción de 24 sujetos, conservada en 3 tubos que contenían uno de los tres anticoagulantes (EDTA, heparina sódica y citrato de sodio) se adulteró con una muestra positiva ante el VIH-1 o una muestra positiva ante el VIH-2 para producir un nivel de reactividad en el margen positivo bajo. Las muestras muestras positivas ante VIH-1 y las muestras positivas ante el VIH-2 se dividieron y se almacenaron refrigeradas (2 °C - 8 °C), a temperatura ambiente (18 °C) o a temperaturas elevadas (30 - 33 °C) y se sometieron a prueba a lo largo de un periodo de 7 días. No se observó ningún efecto específico del anticoagulante en el rendimiento del ensayo con muestras conservadas hasta 7 días a 2 °C - 30 °C.

Como parte de los estudios clínicos con fluido oral, se obtuvo información de los participantes sobre afecciones médicas o afecciones médicas concomitantes, patologías bucales o infecciones virales ajenas al VIH, y otros factores (p. ej., el empleo de productos del tabaco, el empleo de enjuague bucal durante las 24 horas previas a la prueba, medicamentos concomitantes, dentaduras postizas y bebidas o alimentos consumidos inmediatamente antes de la prueba). Ninguno de esos estados patológicos, afecciones médicas u otros factores interfirieron con la sensibilidad de la prueba. En otro estudio de 40 individuos, ni el consumo de alcohol, el lavado de dientes, el empleo de enjuagues bucales o fumar tabaco 5 minutos antes de la prueba demostraron tener efecto alguno sobre la sensibilidad de la prueba.

#### DETECCIÓN DE ANTICUERPOS ANTI VIH-2 EN MUESTRAS DE INDIVIDUOS INFECTADOS CON EL VIH-2

Se obtuvieron un total de 324 muestras de suero/plasma de las cuales se reportó que eran positivas ante el VIH-2; las muestras procedieron de diferentes bancos. Las muestras se sometieron a prueba de EIA anti VIH-1/2 autorizada, EIA anti VIH-2 autorizada, método Western VIH-2 autorizado, método Western VIH-2 y PCR específico de VIH-2. Un total de 6 muestras no demostraron ser positivas ante anticuerpos anti VIH-1 o VIH-2, todas las cuales fueron no reactivas con la prueba para detección de anticuerpos OraQuick ADVANCE®. Dos de las 6 muestras negativas fueron repetidamente reactivas con EIA anti VIH-1/2 autorizado, negativas con EIA anti VIH-2 autorizado e indeterminadas por el método Western VIH-1 autorizado y el método Western VIH-2.

De las 318 muestras restantes, 151 fueron positivas en el método Western VIH-2 y 50 fueron positivas usando un PCR específico de VIH-2. Ciento veintidos muestras produjeron resultados confirmatorios constantes con la infección por VIH-1 y se excluyeron del análisis. Una muestra se catalogó como infección doble sobre la base de una prueba adicional por co-cultivo y no se incluyó en el análisis de sensibilidad. Una muestra, que resultó indeterminada en el método Western VIH-1 y VIH-2, produjo un resultado positivo en el ensayo de radioinmunoprecipitación VIH-2 (RIPA) y también se consideró positiva ante anticuerpos anti VIH-2. La prueba OraQuick ADVANCE® detectó 201/201 (100%) de las muestras de individuos positivos ante VIH-2 confirmados (vea la tabla 6).

En un estudio separado se prepararon un total de 499 muestras de plasma obtenidas de una zona endémica con VIH-2 (Costa de Marfil) como sangre artificiosa y se sometieron a la prueba para detección de anticuerpos OraQuick ADVANCE®, al EIA anti VIH-1/2 autorizado, al EIA anti VIH-2 autorizado, al método Western VIH-1 y al método Western VIH-2. En la tabla 6 se muestra un resumen de los resultados. La prueba para detección de anticuerpos OraQuick ADVANCE® fue reactiva en todas las 27 muestras que fueron repetidamente reactivas con el EIA anti VIH-1/2 autorizado, el EIA anti VIH-2 autorizado y positivas con el método Western VIH-1 y con las tres muestras confirmadas como positivas ante VIH-2 únicamente por el método Western VIH-2. Dos muestras resultaron positivo falso con OraQuick ADVANCE®.

**TABLA 6**  
**Detección de anticuerpos anti VIH-2 en muestras de individuos seropositivos ante el VIH-2 e individuos con alto riesgo de infección por el VIH-2.**

Grupo de prueba	Total de muestras	OraQuick <i>ADVANCE</i> ® reactivo	Repetidamente reactivo con EIA anti VIH-2 autorizado o positivo con PCR VIH-2	Verdadero positivo ante VIH-2 <sup>1</sup>
Positivo ante VIH-2 confirmado	324 <sup>2</sup>	201	201 <sup>3</sup>	201 <sup>4</sup>
Alto riesgo	499	32	33	3
TOTAL	823	233	234	204

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western VIH-2, con confirmación RIPA de resultados indeterminados por el método Western.

<sup>2</sup> Ciento veintidós muestras produjeron resultados confirmatorios constantes con la infección por VIH-1 y se excluyeron del análisis. Además, una muestra se catalogó como infección doble sobre la base de una prueba adicional por cultivo y no se incluyó en el análisis de sensibilidad.

<sup>3</sup> 151 muestras se sometieron a prueba con tan sólo un EIA anti VIH-2. En las 50 muestras restantes se llevó a cabo DNA VIH-2 o PCR RNA, en lugar del EIA. Todos los resultados fueron positivos.

<sup>4</sup> Se confirmó que una muestra era positiva ante el VIH-2 sobre la base de los resultados positivos de un RIPA específico del VIH-2.

Al combinar la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos del estudio de positivos confirmados con la cantidad de resultados reactivos con OraQuick *ADVANCE*® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la sensibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® para la detección de anticuerpos anti VIH-2 en estos estudios fue de  $204/204 = 100\%$  (95% I.C. = 98.2% -100%).

Además, se hicieron pruebas OraQuick *ADVANCE*® con muestras obtenidas por pinchazo de dedo y fluido oral de 3 individuos infectados con el VIH-2, localizados en EE.UU. Las muestras de sangre obtenida por pinchazo y de fluido oral de los tres individuos fueron reactivas con la prueba OraQuick *ADVANCE*®.

## ESPECIFICIDAD

### FLUIDO ORAL

Se llevó a cabo un estudio de especificidad en cuatro centros de ensayo clínico usando muestras de fluido oral recién obtenido de 605 individuos en quienes no se habían llevado a cabo pruebas de detección y que corrían bajo riesgo de infección por el VIH-1. Todas las 605 muestras produjeron correctamente un resultado no reactivo usando la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. De las 3077 muestras negativas ante el VIH de los cuatro centros de estudio que examinaron poblaciones de alto riesgo de infección por el VIH-1, la prueba para detección de anticuerpos OraQuick *ADVANCE*® fue no reactiva en 3069. Los resultados se resumen en la tabla 7.

**TABLA 7**  
**Rendimiento de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en muestras de fluido oral obtenidas de individuos supuestamente negativos ante infección por el VIH**

Grupo de prueba	Total de muestras	No reactivo con OraQuick <i>ADVANCE</i> ®	No reactivo con EIA autorizado	Negativo verdadero <sup>1</sup>
Bajo riesgo	605	605	599 <sup>2</sup>	605
Alto riesgo	3150	3069 <sup>3</sup>	3076 <sup>4</sup>	3077
TOTAL	3755	3674	3675	3682

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western VIH-1 autorizado, con confirmación de resultados indeterminados de manchado Western por RIPA o IFA.

<sup>2</sup> Seis muestras fueron positivo falso con el EIA, cinco con el método Western negativo y una con un manchado indeterminado que se confirmó como negativo por medio de IFA.

<sup>3</sup> Una muestra adicional resultó negativo falso con OraQuick *ADVANCE*® (vea la tabla 1).

<sup>4</sup> Una muestra resultó positivo falso con el EIA, con un manchado de Western negativo.

Al combinar la cantidad de resultados no reactivos OraQuick *ADVANCE*® obtenidos a partir del estudio de poblaciones de bajo riesgo con la cantidad de resultados no reactivos OraQuick *ADVANCE*® obtenidos a partir del estudio de las poblaciones de alto riesgo, se calculó que la especificidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en estos estudios fue de  $3674/3682 = 99.8\%$  (95% I.C. = 99.6% -99.9%).

### PLASMA

Se llevó a cabo un estudio de especificidad en siete centros de ensayo clínico usando muestras de plasma conservadas en EDTA de 1102 individuos en quienes no se había llevado a cabo pruebas de detección y que corrían bajo riesgo de infección por el VIH. Todas las muestras, con la excepción de una, produjeron resultados no reactivos usando la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®. Además, 519 de las 520 muestras negativas ante el VIH de los centros de estudio que examinaron poblaciones de alto riesgo de infección por el VIH-1 también produjeron resultados no reactivos con la prueba para detección de anticuerpos OraQuick *ADVANCE*®. Los resultados del estudio se muestran en la tabla 8.

**TABLE 8**  
**Rendimiento de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® en muestras de plasma obtenidas de individuos supuestamente negativos ante infección por el VIH**

Grupo de prueba	Total de muestras	No reactivo con OraQuick ADVANCE®	No reactivo con EIA autorizado	Negativo verdadero <sup>1</sup>
Bajo riesgo	1102	1101	1096 <sup>2</sup>	1102
Alto riesgo	534	519	516 <sup>3</sup>	520
TOTAL	1636	1620	1612	1622

<sup>1</sup> La confirmación se llevó a cabo por medio del método Western VIH-1 autorizado, con confirmación de resultados indeterminados el método Western por RIPA o IFA.

<sup>2</sup> Seis muestras fueron positivo falso con el EIA, cinco con el método Western negativo y una con un manchado indeterminado que se confirmó como negativo por medio de IFA.

<sup>3</sup> Cuatro muestras fueron positivo falso con el EIA, con 1 negativo y 3 indeterminados por el método Western que se confirmaron como negativos por el IFA.

Al combinar la cantidad de resultados no reactivos OraQuick ADVANCE® obtenidos del estudio de poblaciones de bajo riesgo con el número de resultados no reactivos OraQuick ADVANCE® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la especificidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® en estos estudios fue de 1620/1622 = 99.9% (95% I.C. = 99.6% -99.9%).

#### **SANGRE OBTENIDA POR PINCHAZO DEL DEDO**

Se llevó a cabo un estudio de especificidad en cuatro centros de ensayo clínico usando muestras de sangre recién obtenida por pinchazo de dedo de 1250 individuos en quienes no se había llevado a cabo pruebas de detección y que corrían bajo riesgo de infección por el VIH-1. En el curso de este estudio, se confirmó que dos muestras tenían anticuerpos anti VIH-1 y se retiraron del cálculo de especificidad. Todas las demás muestras produjeron resultados no reactivos usando la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®. Además, todas las 608 muestras negativas ante el VIH -1 de los centros de estudio que examinaron poblaciones de alto riesgo de infección por el VIH-1 también produjeron resultados no reactivos con la prueba para detección de anticuerpos OraQuick ADVANCE®. Los resultados del estudio se muestran en la tabla 9.

**TABLA 9**  
**Rendimiento de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® en muestras de sangre obtenidas por pinchazo de dedo de individuos supuestamente seronegativos ante infección por el VIH**

Grupo de prueba	Total de muestras	No reactivo con OraQuick ADVANCE®	No reactivo con EIA autorizado	Negativo verdadero <sup>3</sup>
Bajo riesgo	1250 <sup>1</sup>	1248	1247 <sup>2</sup>	1248
Alto riesgo	625	608	605	608
TOTAL	1875	1856	1853	1856

<sup>1</sup> Se eliminaron del cálculo de especificidad dos muestras del estudio de bajo riesgo que produjeron resultados reactivos usando la prueba para detección de anticuerpos OraQuick ADVANCE®, resultados repetidamente reactivos usando el EIA autorizado y resultados positivos usando el método Western autorizado.

<sup>2</sup> Una muestra resultó repetidamente reactiva con el EIA, negativa con el método Western.

<sup>3</sup> El estado negativo verdadero se basó en resultados de prueba negativos o indeterminados usando el método Western autorizado.

Al combinar la cantidad de resultados no reactivos con OraQuick ADVANCE® obtenidos a partir de poblaciones de bajo riesgo con la cantidad de resultados no reactivos OraQuick ADVANCE® obtenidos a partir del estudio de poblaciones de alto riesgo, se calculó que la especificidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® en estos estudios fue de 1856/1856 = 100% (95% I.C. = 99.7% -100%).

#### **SUSTANCIAS QUE INTERFIEREN Y AFECCIONES MÉDICAS NO RELACIONADAS**

Con el fin de evaluar el impacto de las afecciones médicas no relacionadas o de las sustancias interferentes sobre la especificidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®, se analizaron 321 muestras de suero/plasma provenientes de una variedad de afecciones médicas no relacionadas con la infección por el VIH y 119 muestras con sustancias interferentes. Los resultados del estudio se muestran en la tabla 10. Una muestra de sujetos seropositivos confirmados ante el VEB, el VHB o el factor reumatoide, una de una mujer multipara, y tres muestras de sujetos con infección confirmada por el VHA produjeron resultados falsos positivos.

Además, se llevó a cabo un estudio para evaluar el efecto potencial de los anticoagulantes sobre la especificidad del ensayo. Se obtuvo sangre por pinchazo de dedo de 24 sujetos seronegativos ante el VIH, en 3 tubos que contenían uno de los siguientes anticoagulantes: EDTA, heparina sódica y citrato de sodio. Las muestras se dividieron y se almacenaron refrigeradas (2 °C - 8 °C), a temperatura ambiente (18 °C) o a temperaturas elevadas (30 °C - 33 °C) y se sometieron a prueba a lo largo de un periodo de 7 días. No se observaron efectos específicos del anticoagulante en el rendimiento del ensayo con muestras conservadas hasta 5 días a horas a 2 °C - 30 °C (vea la tabla 10).



**TABLA 10**  
**Reactividad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® con muestras de individuos con afecciones médicas potencialmente interferentes y muestras con sustancias interferentes**

Enfermedad (n = 321)	Resultados con OraQuick <i>ADVANCE</i> ®	
	Reactivo	No reactivo
Mujeres multíparas	1 <sup>2</sup>	14
Anticuerpo antinuclear (ANA)	0	17
Lupus	0	15
Factor reumatoide	1 <sup>2</sup>	17
Citomegalovirus (CMV)	0	15
Virus de Epstein Barr (VEB)	1 <sup>2</sup>	14
Virus de la hepatitis A (VHA)	3 <sup>1</sup>	17
Virus de la hepatitis B (VHB)	1 <sup>2</sup>	16
Virus de la hepatitis C (VHC)	0	15
Virus linfotrópico de las células T humanas tipo I (HTLV-I)	0	15
Virus linfotrópico de las células T humanas tipo II (HTLV-II)	0	15
Rubéola	0	15
Gamopatías IgG	0	13
Gamopatías IgM	0	12
Sífilis	0	15
Toxoplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Transfusiones múltiples	0	10
Hemofilia	0	10
Virus Herpes Simplex	0	5
Cirrosis	0	5
Paciente de diálisis	0	4
Cáncer de colon	0	4
HTLV I/II	0	2
Clamidia	0	3
Anticuerpo anti scl o anti rnp	0	3
Cáncer de mama	0	1
Anticuerpo anti DNA	0	1
Gonorrea	0	1
Sustancias interferentes (n = 211)		
Nivel elevado de bilirrubina	0	20
Nivel elevado de hemoglobina	0	20
Nivel elevado de triglicéridos	0	20
Nivel elevado de proteína	0	20
Contaminación bacteriana	0	25
Hemólisis visual (hemolítico)	0	5
Ictericia	0	5
Lipemia	0	4
Heparina sódica <sup>3</sup>	0	24
EDTA <sup>3</sup>	0	24
Citrato de sodio <sup>3</sup>	0	24

<sup>1</sup> Un total de 3 de las 20 muestras de VHA fueron falsamente reactivas con OraQuick *ADVANCE*®. Dos de las 3 muestras fueron no reactivas con OraQuick *ADVANCE*® en la lectura de los 20-25 minutos y reactivas en la lectura de los 55-60 minutos. El resto de la muestra fue reactivo en ambas lecturas.

<sup>2</sup> Una de las muestras fue no reactiva con OraQuick *ADVANCE*® en la lectura de los 20-25 minutos y reactiva en la lectura de los 55-60 minutos.

<sup>3</sup> El máximo tiempo de lectura del ensayo OraQuick *ADVANCE*® para estas muestras fue de 40 minutos. Esto se basó en que la muestra se almacenó 5 días a 2 °C - 30 °C.

Como parte de los estudios clínicos con fluido oral, se obtuvo información de los participantes sobre enfermedades o afecciones médicas concomitantes, patologías bucales o infecciones virales ajenas al VIH, y otros factores (p. ej., el empleo de productos del tabaco, el empleo de enjuague bucal durante las 24 horas previas a la prueba, medicamentos concomitantes, dentaduras postizas y bebidas o alimentos consumidos inmediatamente antes de la prueba). Ninguno de esos estados patológicos, afecciones médicas u otros factores interfirieron con la especificidad de la prueba. En un estudio separado de 40 individuos, el consumo de alcohol, el lavado de dientes, el empleo de enjuagues bucales o fumar tabaco 5 minutos antes de la prueba no demostraron tener efecto alguno sobre la especificidad de la prueba.

## REPRODUCIBILIDAD

La reproducibilidad de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® se comprobó en tres centros utilizando 3 lotes del dispositivo en 3 días diferentes con 9 operadores (por centro). Se sometió a prueba un panel codificado en ciego que consistió en 5 muestras de sangre artificiosa (4 seropositivas y 1 seronegativa). Los resultados de las pruebas se anotaron a los 20-25 minutos y a los 55-60 minutos. Se llevaron a cabo un total de 405 pruebas (135/centro) con un total de 81 pruebas por miembro del panel. La reproducibilidad general de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® fue 405/405 = 100%. La concordancia entre los límites de lectura especificados para el ensayo fue del 99.8% (404/405); un solo miembro del panel de positivo bajo ante el VIH-1 fue no reactivo en la lectura de los 20-25 minutos y reactivo en la lectura de los 55-60 minutos.

## RESULTADOS DEL ESTUDIO CON USUARIOS SIN CAPACITACIÓN

Se llevó a cabo un estudio con “usuarios no capacitados” en el cual se proporcionó a los participantes únicamente las instrucciones de la prueba y se les pidió que llevaran a cabo pruebas de un panel ciego que consistió en 6 muestras aleatorizadas de plasma humano con tres niveles diferentes (negativo, positivo bajo y positivo alto de reactividad con la prueba OraQuick *ADVANCE*®). No se les impartió ninguna capacitación a los participantes en el empleo de la prueba ni en la interpretación de los resultados de la prueba; tampoco se les permitió observar la ejecución de los controles del juego llevada a cabo por el Coordinador del Estudio. El protocolo del estudio estipuló que se excluyera de la participación a personal de laboratorio médico profesionalmente capacitado o a personas con experiencia previa en el empleo del dispositivo OraQuick *ADVANCE*®. Se inscribió a un total de 100 participantes de un total de cuatro centros, los cuales representaron una población demográfica diversa (en cuanto a educación, etnia, edad, sexo, etc.).

La tasa de resultados correctos para el estudio en general fue del 98.6% (592/600). Consulte la tabla a continuación para un resumen del rendimiento relativo al tipo de muestra. Los ocho resultados incorrectos se atribuyeron a seis participantes. De esos seis participantes, cuatro obtuvieron 5 de 6 resultados correctos y dos participantes obtuvieron 4 de 6 resultados correctos.











Tasa de resultados correctos con usuarios no capacitados			
Negativo	Positivo bajo	Positivo alto	Total
98.5% (197/200)	98.0% (196/200)	99.5% (199/200)	98.6% (592/600)
95% I.C. (95.7% - 99.7%)	95% I.C. (95.0% - 99.5%)	95% I.C. (97.3% - 99.9%)	95% I.C. (97.4% - 99.4%)

Se reportaron 1.7% (10/600) resultados inválidos, y 5 de los 10 resultados inválidos se atribuyeron a un solo participante. Todas las pruebas se repitieron con éxito, con 8/10 de las pruebas repetidas interpretadas correctamente. Los 2 resultados incorrectos repetidos se atribuyeron a un solo participante. Si bien la mayoría de los participantes pudieron obtener resultados válidos con el primer intento, uno de los 100 participantes obtuvo cinco resultados de prueba inválidos de las seis pruebas realizadas. Se observó que el error del usuario en algunos casos se atribuyó a confusión con los viales de muestra. Estos resultados apoyan la necesidad de entrenar al personal ajeno al laboratorio en el manejo de muestras múltiples en un entorno de laboratorio donde las muestras se analizan en lotes. Como parte del estudio con usuarios no capacitados, se completó un cuestionario de retroalimentación de los participantes. Todos los participantes calificaron la prueba como ‘fácil de usar’ y se consideraron ‘capaces de realizar la prueba correctamente’.

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## EXPLICACIÓN DE LOS SÍMBOLOS

 Código de lote	 Producto sanitario para diagnóstico <i>in vitro</i>
 Número de catálogo	 Fabricante
 Atención, consulte los documentos adjuntos	 Límites de temperatura
 Control VIH negativo	 Usar antes de
 Control VIH-1 positivo	 Control VIH-2 positivo

Fabricado por:



**OraSure Technologies, Inc.**

220 East First Street, Bethlehem, PA 18015 EE.UU.  
 1-(800) ORASURE (800-672-7873) o 610-882-1820  
[www.orsure.com](http://www.orsure.com)



## Kit Controls

Read this package insert and the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results. Before performing testing, all operators **MUST** read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.<sup>1</sup>

### NAME AND INTENDED USE

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls are quality control reagents for use only with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

Run the Kit Controls under the following circumstances:

- each new operator prior to performing testing on patient specimens,
- when opening a new test kit lot,
- whenever a new shipment of test kits is received,
- if the temperature of the test kit storage area falls outside of 2° - 27°C (35° - 80°F),
- if the temperature of the testing area falls outside of 15° - 37°C (59° - 99°F), and
- at periodic intervals as dictated by the user facility.

It is the responsibility of each laboratory using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### SUMMARY AND EXPLANATION OF THE KIT CONTROLS

OraQuick *ADVANCE*® Kit Controls are human plasma-based reagents. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Positive Controls will produce a Reactive test result and have been manufactured to produce a very faint Test ("T") line. The Negative Control will produce a non-reactive test result. Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

### MATERIALS PROVIDED

#### OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls

Each Kit Control box contains a package insert and three vials (one HIV-1 positive control, one HIV-2 positive control and one negative control) as described below:

#### HIV-1 Positive Control

One black-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-1, diluted in a defibrinated pool of normal human plasma. Preservative: ProClin 5000. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

## HIV-2 Positive Control

One red-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-2, diluted in a defibrinated pool of normal human plasma. Preservative: ProClin 5000. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

## Negative Control

One white-capped vial containing 0.2 mL of defibrinated pool of normal human plasma negative for antibodies to HIV-1 and HIV-2. Preservative: ProClin 5000. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

## MATERIALS REQUIRED AND PROVIDED in the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial

Reusable Test Stands

Specimen Collection Loops

Subject Information Pamphlets

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Package Insert

Customer Letter

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes

Latex, vinyl or nitrile disposable gloves

Biohazard waste container

Clean, disposable, absorbent workspace cover

## WARNINGS AND PRECAUTIONS

### For *in vitro* Diagnostic Use

1. Read this package insert and the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
2. Handle specimens, and materials contacting specimens, as if potentially infectious biological materials in accordance with "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings".<sup>1</sup>
3. Handle the Kit Controls, and materials contacting the Kit Controls, as if capable of transmitting infectious agents.
4. Do not drink, eat, or smoke in areas where the Kit Controls are being handled.
5. Wear disposable gloves while handling specimens. Wash hands thoroughly after performing each test. Dispose of gloves in a biohazard waste container after use.
6. Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.** For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings".<sup>1</sup>
7. Wipe all spills thoroughly with a freshly prepared solution of 10% bleach or other appropriate disinfectant.<sup>2</sup>
8. Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

## STORAGE INSTRUCTIONS

Store the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls at 2-8°C (35-46°F). Do not use Kit Controls beyond the expiration date printed on the outer carton. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original container at 2-8°C (35-46°F) after use.

**Dispose of unused portions of opened Kit Control vials after eight weeks.**

## DIRECTIONS FOR USE

### General Test Preparation

Perform procedures indicated in the *Set-Up Your Workspace* and *General Test Preparation* sections of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test package insert.

### TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the round end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**  
**NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard the used loop in a biohazard waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial.**
5. Leave the Test Device in the Developer Solution Vial and start a timer. **Do not remove the Test Device from the vial until you have read the results.** Read the results after 20 minutes but not more than 40 minutes in a fully lighted area. Read the results as described in the *Test Result* and *Interpretation of Test Result* sections of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit product insert.
6. Dispose of the used Developer Solution Vial and the Test Device in a biohazard waste container.
7. Reseal the Kit Control reagent vials and store them in their original container at 2°- 8°C (35°- 46°F).

## EXPECTED RESULTS

### Negative Control:

The Negative Control will produce a Non-Reactive test result. A line should be present in the Result Window in the area adjacent to only the triangle labeled "C." This indicates a Non-Reactive test result.

### HIV-1 Positive Control:

The HIV-1 Positive Control will produce a Reactive test result and has been manufactured to produce a very faint Test ("T") line. A line should be present in the Result Window in the area adjacent to the triangle labeled "C" **and** a line should appear in the area adjacent to the triangle labeled "T." This indicates a Reactive test result. The lines will not necessarily be the same intensity.

### HIV-2 Positive Control:

The HIV-2 Positive Control will produce a Reactive test result and has been manufactured to produce a very faint Test ("T") line. A line should be present in the Result Window in the area adjacent to the triangle labeled "C" **and** a line should appear in the area adjacent to the triangle labeled "T." This indicates a Reactive test result. The lines will not necessarily be the same intensity.

**NOTE: If the test result for either the Negative Control or the HIV-1 Positive Control or the HIV-2 Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and contact OraSure Technologies Customer Service.**

## LIMITATIONS

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls are quality control reagents for use only with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

## BIBLIOGRAPHY

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2. Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. *Appl Env Microbiol* 1981; 42:762-7.

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Prueba rápida de detección de anticuerpos anti VIH-1/2

## Controles para los juegos de materiales de prueba

Lea este instructivo y el instructivo del juego de materiales de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® en su totalidad antes de usar el producto. Siga las instrucciones al pie de la letra. De lo contrario, los resultados de la prueba podrían ser inexactos. Antes de realizar las pruebas, todos los operadores DEBEN leer y familiarizarse con las precauciones universales para prevenir la transmisión del virus de la inmunodeficiencia humana, el virus de la hepatitis B y otros patógenos transmitidos por la sangre en los entornos de atención de la salud<sup>1</sup>.

### NOMBRE Y USO PREVISTO

Los controles para el juego de materiales de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® consisten en reactivos para el control de la calidad que deben utilizarse únicamente con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®.

Utilice los controles para el juego de materiales en las siguientes circunstancias:

- Con cada operador nuevo antes de realizar pruebas en muestras de pacientes,
- Cuando abra un lote nuevo de juegos de materiales de prueba,
- Cuando se reciba un nuevo envío de juegos de materiales de prueba,
- Si la temperatura del área de almacenamiento del juego de materiales de la prueba se encuentra fuera del margen de 2 °C-27 °C (35 °F- 80 °F),
- Si la temperatura del área de pruebas se encuentra fuera del margen de 15 °C- 37 °C (59 °F- 99 °F),
- A intervalos periódicos según lo dicten las instalaciones del usuario.

Recae sobre cada laboratorio que utilice la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE® la obligación de establecer un programa de control de calidad adecuado para asegurar el rendimiento del dispositivo en el lugar y situaciones de uso específicos.

### RESUMEN Y EXPLICACIÓN DE LOS CONTROLES PARA JUEGO DE MATERIALES DE PRUEBA

Los controles para el juego de materiales OraQuick ADVANCE® son reactivos elaborados con plasma humano. Los controles se formulan y elaboran específicamente para asegurar el rendimiento de la prueba y se usan para verificar la habilidad del usuario para llevar a cabo la prueba e interpretar los resultados correctamente. Los controles VIH-1 y VIH-2 positivo producen un resultado de prueba reactivo y han sido elaborados para producir una muy tenue línea de prueba ("T"). El control negativo produce un resultado de prueba no reactivo. El empleo de reactivos de control para juegos de materiales de prueba de otros fabricantes podría no producir los resultados requeridos y por lo tanto no cumplir con las disposiciones de un programa de control de calidad adecuado para la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®.

### MATERIALES SUMINISTRADOS

**Controles para el juego de materiales de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick ADVANCE®**

Cada caja de control para juego de materiales contiene un instructivo y tres frascos (un control de VIH-1 positivo, un control de VIH-2 positivo y un control negativo) como se describe a continuación:

#### Control VIH-1 positivo

Un frasco con tapa negra que contiene 0.2 ml de plasma humano fotoquímicamente inactivado positivo ante los anticuerpos VIH-1, diluido en una mezcla de plasma humano desfibrinado. Conservante: ProClin 5000. Negativo ante el antígeno de superficie de la hepatitis B y el anticuerpo hepatitis C.



## Control VIH-2 positivo

Un frasco con tapa roja que contiene 0.2 ml de plasma humano fotoquímicamente inactivado positivo ante los anticuerpos VIH-2, diluido en una mezcla de plasma humano desfibrinado. Conservante: ProClin 5000. Negativo ante el antígeno de superficie de la hepatitis B y el anticuerpo hepatitis C.

## Control negativo

Un frasco con tapa blanca que contiene 0.2 ml de mezcla de plasma humano desfibrinado normal negativo anti anticuerpos VIH-1 y VIH-2. Conservante: ProClin 5000. Negativo ante el antígeno de superficie de la hepatitis B y el anticuerpo hepatitis C. Manto protector limpio, desechable, absorbente sobre el área de trabajo.

## MATERIALES REQUERIDOS Y SUMINISTRADOS en el juego de materiales para la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®

Bolsas divididas, cada una con un dispositivo para prueba, un paquete de absorbente y un frasco de solución reveladora  
Soportes para prueba reutilizables  
Aros para colección de muestras  
Folletos de información para el paciente  
Instructivo de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®  
Carta al cliente

## MATERIALES NECESARIOS NO SUMINISTRADOS

Cronómetro o reloj capaz de medir 20 a 40 minutos  
Guantes desechables de látex, vinilo o nitrilo  
Envase para desechar peligros biológicos  
Manto protector limpio, desechable, absorbente sobre el área de trabajo

## ADVERTENCIAS Y PRECAUCIONES

### Para diagnóstico in vitro

1. Lea este instructivo y el instructivo del paquete de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® en su totalidad antes de usar el producto. Siga las instrucciones al pie de la letra. De lo contrario, los resultados de la prueba podrían ser inexactos.
2. Maneje las muestras y los materiales que entren en contacto con las muestras como si fuesen materiales biológicos potencialmente infecciosos, de conformidad con las precauciones universales para prevenir la transmisión del virus de la inmunodeficiencia humana, el virus de la hepatitis B y otros patógenos transmitidos por la sangre en los entornos de atención de la salud<sup>1</sup>.
3. Maneje los controles y los materiales que entren en contacto con los controles como si fuesen capaces de transmitir agentes infecciosos.
4. No coma, beba ni fume en áreas donde se están manipulando controles.
5. Use guantes desechables mientras maneja las muestras. Lávese las manos muy bien después de llevar a cabo cada prueba. Elimine los guantes en un envase para peligros biológicos después de usarlos.
6. Elimine todos los controles utilizados en las pruebas en un envase para peligros biológicos. El método recomendado para eliminar los peligros biológicos es esterilizar en autoclave por 1 hora como mínimo a 121 °C. Los materiales desechables se pueden incinerar. Los desperdicios líquidos se pueden mezclar con desinfectantes químicos apropiados. Se recomienda una solución recién preparada de blanqueador al 10% (solución de hipoclorito de sodio al 0.5%). Conceda 60 minutos para la descontaminación eficaz. **NOTA: No someta a autoclave ninguna solución que contenga blanqueador.** Para obtener información adicional sobre seguridad biológica, consulte "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Setting"<sup>1</sup>.

7. Limpie todo derrame completamente con una solución recién preparada de blanqueador al 10% o algún otro desinfectante apropiado<sup>2</sup>.
8. El empleo de reactivos para control fabricados por otras fuentes puede no producir los resultados requeridos y, por lo tanto, no satisfacer el requisito de un programa de control de calidad adecuado para la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

## INSTRUCCIONES PARA EL ALMACENAMIENTO

Almacene los controles para el juego de materiales de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® a 2 °C - 8 °C (35 °F - 46 °F). No use los controles después de la fecha de vencimiento impresa en la caja exterior. Abra los frascos de control únicamente si va a realizar las pruebas. Tape los frascos y almacénelos en su envase original a 2 °C - 8 °C (35 °F - 46 °F) después de usarlos.

**Elimine las porciones no utilizadas de los frascos de control después de ocho semanas.**

## MODO DE EMPLEO

### Preparación general para la prueba

Realice los procedimientos indicados en las secciones Preparación del lugar de trabajo y Preparación general para la prueba que aparecen en el instructivo de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

## PROCEDIMIENTO DE PRUEBA

1. Abra un frasco de control que contenga el reactivo de control.
2. Introduzca el extremo redondeado de un aro para la obtención de muestras en el frasco de reactivo de control. Inspeccione el aro visualmente para verificar que esté completamente lleno de reactivo de control. **Use un aro de obtención de muestra individual para cada reactivo de control.**  
**NOTA: Los reactivos de control para juegos son de color transparente a trigo. No lo use si el reactivo se ve turbio o descolorido.**
3. Sumerja el aro de obtención de muestra lleno de reactivo de control en la solución reveladora dentro del frasco de solución reveladora. Use el aro para la obtención de muestras para revolver la muestra con la solución reveladora. Retire el aro para la obtención de muestras del frasco de solución reveladora y deseche el aro usado en un envase para peligros biológicos.
4. Retire el dispositivo de prueba de la bolsa dividida sin tocar la paleta. Inserte el dispositivo de prueba, con la paleta primero, en el frasco de solución reveladora que contiene la muestra. **Asegúrese de que la ventanilla de resultados esté hacia delante y que la paleta toque el fondo del frasco de la solución reveladora.**
5. Deje el dispositivo de prueba en el frasco de la solución reveladora y ponga un cronómetro. **No retire el dispositivo de prueba del frasco hasta que haya leído los resultados.** Lea los resultados después de 20 minutos, pero no más de 40 minutos en un lugar completamente iluminado. Lea los resultados de prueba como se describe en las secciones Resultado de la prueba e interpretación del resultado de la prueba en el instructivo de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.
6. Deseche el frasco de solución reveladora y el dispositivo de prueba en un envase para peligros biológicos.
7. Tape los frascos de reactivo de control y almacénelos en su envase principal a una temperatura de 2 °C - 8 °C (35 °F - 46 °F).

## RESULTADOS ESPERADOS

### Control negativo:

El control negativo produce un resultado de prueba no reactivo. Debe haber una línea en la ventana de resultados en el área adyacente al único triángulo que dice "C". Esto indica un resultado de prueba no reactivo.

### Control VIH-1 positivo:

El control VIH-1 positivo produce un resultado de prueba reactivo y ha sido elaborado para producir una muy tenue línea de prueba ("T"). Debe haber una línea en la ventana de resultados en el área adyacente al triángulo que dice "C" **y** debe aparecer una línea en el área adyacente al triángulo que dice "T". Esto indica un resultado de prueba reactivo. Las líneas no serán necesariamente de la misma intensidad.

### Control VIH-2 positivo:

El control VIH-2 positivo produce un resultado de prueba reactivo y ha sido elaborado para producir una muy tenue línea de prueba ("T"). Debe haber una línea en la ventana de resultados en el área adyacente al triángulo que dice "C" **y** debe aparecer una línea en el área adyacente al triángulo que dice "T". Esto indica un resultado de prueba reactivo. Las líneas no serán necesariamente de la misma intensidad.

**NOTA: Si el resultado de prueba del control negativo o del control VIH-1 positivo o el control VIH-2 positivo no es el esperado, se deberá repetir la prueba usando un nuevo dispositivo de prueba, frasco de solución reveladora y muestra de control. Si el resultado de prueba de cualquiera de los controles no es el esperado al repetir la prueba, suspenda la prueba y comuníquese con el departamento de servicio al cliente de OraSure Technologies.**

## LIMITACIONES

Los controles para el juego de materiales de la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*® consisten en reactivos para el control de la calidad que deben utilizarse únicamente con la prueba rápida de detección de anticuerpos anti VIH-1/2 OraQuick *ADVANCE*®.

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2. Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. Appl Env Microbiol 1981; 42:762-7.

Fabricado por:



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## **SUBJECT INFORMATION**

**What You Should Know About HIV  
and the OraQuick *ADVANCE*®  
Rapid HIV-1/2 Antibody Test  
Prior to Being Tested**



## **INFORMACIÓN PARA EL PACIENTE**

**Lo que debe saber acerca del VIH  
y OraQuick *ADVANCE*®  
Prueba de detección de  
anticuerpos Rapid HIV-1/2  
antes de que le hagan la prueba**

## ■ What should I know before I get tested?

Your healthcare provider is the best person to answer your questions about HIV, the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, and other testing options.

You have a choice of the type of test to use. When you are tested for HIV, a specimen will be collected and checked for HIV antibodies. The presence of HIV antibodies in your body means that you have been infected with the virus that causes AIDS.

You should be aware that the presence of HIV antibodies can be detected in many ways. Ask your healthcare provider for the information you need to make good choices. Some questions answered in this pamphlet are:

- What are HIV and AIDS?
- How does someone get HIV?
- How can I avoid becoming infected?
- Why should I get tested?
- What is the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and how is it done?
- What does a preliminary positive result mean?
- What does a negative result mean?
- Where can I get more Information?

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## ■ ¿Qué debo saber antes de que me hagan la prueba?

Su proveedor médico es la persona que mejor puede responder a sus preguntas sobre el VIH, la prueba de detección de anticuerpos OraQuick *ADVANCE*® Rapid HIV-1/2 y otras pruebas alternativas.

Usted decide qué tipo de prueba desea que le hagan. Cuando le hacen la prueba de VIH, se le toma una muestra que se analiza para detectar la presencia de anticuerpos contra el VIH. La presencia de anticuerpos contra el VIH en su cuerpo significa que usted está infectado con el virus que causa el SIDA.

Debe saber que la presencia de anticuerpos contra el VIH se puede detectar de varias maneras. Pida a su proveedor médico la información que necesita para tomar buenas decisiones. Algunas de las preguntas que se contestan en este folleto son:

- ¿Qué son el VIH y el SIDA?
- ¿Cómo se contagian las personas con el VIH?
- ¿Cómo puedo evitar contagiarme?
- ¿Por qué debo hacerme una prueba?
- ¿Qué es la prueba de detección de anticuerpos OraQuick *ADVANCE*® Rapid HIV-1/2 y cómo se hace?
- ¿Qué significa un resultado preliminar positivo?
- ¿Qué significa un resultado negativo?
- ¿Dónde puedo obtener más información?

## ■ What are HIV and AIDS?

HIV is the human immunodeficiency virus. HIV is the virus that causes AIDS (acquired immunodeficiency syndrome). It is possible for a person to have the virus for months or years before any signs of illness appear. The virus weakens the body's ability to fight off infections. As a result, people with AIDS develop serious infections and cancers. These illnesses make them very sick and can eventually kill them.

## ■ How does someone get HIV?

HIV spreads through contact with blood, semen, vaginal fluids, or breast milk from infected people. Contact can come from unsafe sex. It can also come from sharing used needles and syringes. Infected women can pass the virus to their babies during pregnancy, childbirth, and breast feeding. It is also possible to become infected with HIV through a blood transfusion, although this is now very rare.

People do not become infected with HIV through everyday casual contact with people at school, work, home, or anywhere else. The virus is not spread from contact with sweat, tears, saliva, or a casual kiss from an infected person (deep, or "French" kissing is not advised). Nor can people become infected from contact with forks, cups, clothes, phones, toilet seats, or other things used by someone who is infected with HIV. People do not become infected from eating food prepared by an HIV-infected person. People have not become infected with HIV through insect bites.

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## ■ ¿Qué son el VIH y el SIDA?

El VIH es el virus de inmunodeficiencia humana. El VIH es el virus que causa el SIDA (síndrome de inmunodeficiencia adquirida). Es posible que una persona tenga el virus durante meses o años antes de que presente algún síntoma de la enfermedad. El virus debilita la capacidad del cuerpo para combatir infecciones. Como resultado, las personas con SIDA desarrollan infecciones graves y cánceres. Estas enfermedades les enferman gravemente y eventualmente pueden matarles.

## ■ ¿Cómo se contagian las personas con el VIH?

El VIH se disemina a través del contacto con la sangre, el semen, los fluidos vaginales o la leche materna de las personas infectadas. El contacto puede originarse de las prácticas sexuales sin protección. También puede provenir de compartir agujas y jeringas usadas. Las mujeres infectadas pueden pasar el virus a su bebé durante el embarazo, el parto y la lactancia. También es posible infectarse con el VIH a través de las transfusiones sanguíneas, aunque en la actualidad esto es muy raro.

No es posible infectarse con el VIH a través del contacto casual cotidiano con las personas en la escuela, el trabajo, el hogar u otro lugar. El virus no se transmite a través del contacto con sudor, lágrimas, saliva o el beso casual de una persona infectada (no se recomiendan los besos profundos o con la lengua). Tampoco es posible infectarse con tenedores, tazas, ropa, teléfonos, asientos de inodoro o con otras cosas usadas por una persona infectada con el VIH. No es posible infectarse por comer la comida preparada por una persona infectada con el VIH. No se han infectado personas con el VIH a través de las picaduras de insectos.

## ■ How can I avoid becoming infected?

The best way to avoid getting HIV is to avoid activities that would allow the virus to be passed to you. By following these suggestions, you will lower your risk of getting HIV:

- The only way to avoid sexual exposure to HIV is to have sex with an uninfected partner or to abstain.
- If you are not certain that your sex partner is uninfected, you should use a latex condom correctly every time you have sex.
- Do not share needles or syringes.

## ■ Why should I get tested?

You cannot generally tell by looking at someone whether he or she has an HIV infection. A person can be infected with HIV and not know it. The virus may take time to show its effects. A person can have HIV for ten years or more before the symptoms of AIDS appear. The only way to be confident that you are not infected is to get an HIV test.

It is important to find out if you are infected with HIV so that you do not infect someone else. If you know you are infected with HIV, you can avoid any activity that may pass it on.

It is also important to find out if you are infected with HIV so that you can receive good medical care. There are medicines that can help keep you healthy even though you are infected with the HIV virus.

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## ■ ¿Cómo puedo evitar contagiarme?

La mejor manera de prevenir el contagio es evitar aquellas actividades que permitirían el paso del virus a su cuerpo. Si sigue estas recomendaciones, reducirá su riesgo de contagiarse con el VIH:

- La única manera de evitar la exposición al VIH a través del sexo es tener relaciones sexuales con un compañero que no esté infectado o abstenerse.
- Si no tiene la certeza de que su compañero sexual no está infectado, debe usar correctamente un condón de látex cada vez que tenga relaciones sexuales.
- No comparta agujas ni jeringas.

## ■ ¿Por qué debo hacerme una prueba?

Generalmente no es posible determinar si una persona está infectada con el VIH sólo con mirarla. Una persona puede estar infectada y no saberlo. El virus puede tardar tiempo para causar su efecto. Una persona puede tener el VIH durante diez o más años antes de que se manifiesten los síntomas del SIDA. La única manera de tener la certeza de que no está infectado es haciéndose una prueba de detección del VIH.

Es importante que sepa si está infectado con el VIH para que no infecte a otras personas. Si usted sabe que está infectado con el VIH, puede evitar toda actividad que pueda diseminarlo.

También es importante que sepa si está infectado con el VIH para que reciba una buena atención médica. Hay medicinas que pueden ayudarle a mantenerse sano aunque esté infectado con el VIH.

## ■ What are my options for HIV testing?

OraQuick *ADVANCE*® provides a rapid HIV test result (in as little as 20 minutes) and in some settings a result is needed quickly, such as in hospital emergency rooms. However, in settings where a rapid HIV test is not needed, alternative tests can be done. You also have a choice of having another type of test that would require you to wait about a week for your results. This type of test can be done using a sample of blood taken from your vein, a sample of oral fluid taken from your mouth, or a sample of urine.

## ■ What is the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and how is it done?

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is used to see if a sample of your oral fluid or blood contains HIV antibodies. If you decide to have an OraQuick *ADVANCE*® test, your healthcare provider will collect an oral fluid sample or take a small droplet of blood from your finger, or draw blood from your vein, run the test, and give the results to you during the same visit. The OraQuick *ADVANCE*® test is very accurate. However, additional testing is necessary to confirm a preliminary positive result.

Complete information about the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test device is available from your testing counselor or healthcare provider.

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## ■ ¿Cuáles son mis opciones respecto a las pruebas de detección del VIH?

OraQuick *ADVANCE*® es una prueba de detección del VIH que da resultados rápidos (puede ser apenas 20 minutos), y en algunas circunstancias el resultado se necesita rápidamente, como por ejemplo en las salas de emergencia de los hospitales. Sin embargo, en los lugares en los que no sea necesaria una prueba rápida de detección del VIH, se pueden hacer pruebas alternativas. También tiene la opción de hacerse otro tipo de prueba en la que requeriría esperar aproximadamente una semana para obtener los resultados. Este tipo de prueba se puede hacer en una muestra de sangre obtenida de su vena, una muestra de fluido oral tomada de su boca o una muestra de orina.

## ■ ¿Qué es la prueba para detección de anticuerpos OraQuick *ADVANCE*® Rapid HIV-1/2 y cómo se lleva a cabo?

La prueba para detección de anticuerpos OraQuick *ADVANCE*® Rapid HIV-1/2 se usa para determinar si una muestra de fluido oral o de sangre contiene anticuerpos anti VIH. Si usted decide hacerse una prueba para detección de anticuerpos OraQuick *ADVANCE*®, su proveedor de atención de la salud obtendrá una muestra de su fluido oral, o le sacará una pequeña gota de sangre del dedo, o le tomará una muestra de sangre de una vena, llevará a cabo la prueba y le dará el resultado durante la misma consulta. La prueba OraQuick *ADVANCE*® es muy precisa. Sin embargo, en el caso de que el resultado preliminar sea positivo, se requerirán otras pruebas para confirmarlo.

Su asesor de pruebas o su proveedor médico tiene información completa sobre la prueba para detección de anticuerpos OraQuick *ADVANCE*® Rapid HIV-1/2.



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### ■ **What does a PRELIMINARY POSITIVE result mean?**

A PRELIMINARY POSITIVE result suggests that antibodies to HIV may be present in your blood or oral fluid. If you receive a PRELIMINARY POSITIVE result on the test, you will need to have another test to confirm the OraQuick *ADVANCE*® test result. You will also be encouraged to take precautions to avoid any chance of spreading HIV until your test result is confirmed.

If you are found to be infected, you may benefit from special medical care. New treatments can help keep you healthy, even though you are infected with HIV. See a doctor, even if you don't feel sick. A doctor can help you to live longer. Other tests can tell you how strong your immune system is and what treatments might be best for you. Some people stay healthy for a long time with HIV. Others may become ill more rapidly. Be careful not to pass HIV on to others.

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### ■ **¿Qué significa un resultado PRELIMINAR POSITIVO?**

Un resultado PRELIMINAR POSITIVO sugiere que posiblemente haya anticuerpos contra el VIH en su sangre o fluido oral. Si usted recibe un resultado PRELIMINAR POSITIVO, necesitará someterse a otra prueba para confirmar los resultados de la prueba OraQuick *ADVANCE*®. También se le recomendará que tome precauciones para evitar toda probabilidad de diseminar el VIH hasta que se confirmen los resultados de su prueba.

Si se determina que usted está infectado, se podrá beneficiar si recibe atención médica especial. Existen nuevos tratamientos que pueden ayudarle a mantenerse sano, aunque esté infectado con el VIH. Consulte a un médico, aunque no se sienta enfermo. Un médico puede ayudarle a prolongar su vida. Otras pruebas pueden indicarle qué tan fuerte es su sistema inmunitario y qué tratamientos pueden ser los mejores para usted. Algunas personas infectadas con el VIH se conservan sanas durante mucho tiempo. Otras se pueden enfermar más rápidamente. Tenga cuidado de no transmitir el VIH a otras personas.

### ■ What does a **NEGATIVE** result mean?

A **NEGATIVE** result means that this test did not detect HIV antibodies in your blood or oral fluid. However, in some cases HIV infection cannot be ruled out completely. If you recently (within 3 months) had any of the contacts described in the “How does someone get HIV?” section of this pamphlet it is still possible that you are infected with HIV. This is because your body can take several months after you are infected to make HIV antibodies. If you became infected only recently, there may not have been enough time to develop antibodies that can be detected by the test. You should consider getting tested again in three to six months to be sure you are not infected. If you had none of the contacts that transmit HIV in the three months before your test, a negative test result means you were not infected with HIV at the time of testing. Ask your healthcare provider to help you understand what your result means for you.

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### ■ ¿Qué significa un resultado **NEGATIVO**?

Un resultado **NEGATIVO** significa que esta prueba no detectó anticuerpos contra el VIH en su sangre o fluido oral. Sin embargo, en algunos casos la infección con el VIH no se puede descartar completamente. Si recientemente (en los últimos 3 meses) ha tenido alguno de los contactos que se describen en la sección “¿Cómo se contagian las personas con el VIH?” de este folleto, aún es posible que usted esté infectado con el VIH. Esto se debe a que su cuerpo puede requerir varios meses después de infectarse para producir anticuerpos contra el VIH. Si se infectó recientemente, es posible que no haya transcurrido suficiente tiempo para desarrollar los anticuerpos que se detectan en la prueba. Debe considerar repetirse la prueba en tres a seis meses para estar seguro de que no está infectado. Si no ha tenido ninguno de los contactos que pueden transmitir el VIH durante los tres meses anteriores a su prueba, un resultado negativo significa que no estaba infectado con el VIH en el momento que se hizo la prueba. Pida a su proveedor médico que le ayude a entender lo que sus resultados significan para usted.

## ■ Where can I get more information?

If you have any questions, ask your healthcare provider. You can also call the National AIDS Hotline at 1-800-342-AIDS (1-800-342-2437) to talk with an HIV specialist. They can give you quick, private answers at any time, day or night. Your local health department is another place to go for information. An AIDS service organization near you can also be a good source for information, education, and help.

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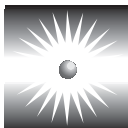
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## ■ ¿Dónde puedo obtener más información?

Si tiene preguntas, hable con su proveedor médico. También puede llamar a la Línea Directa Nacional del SIDA (National AIDS Hotline) al teléfono 1-800-342-AIDS (1-800-342-2437) para hablar con uno de los especialistas en el VIH. Ellos pueden darle respuestas rápidas y privadas en cualquier momento, día o noche. El departamento de salud de su localidad es otro sitio al que puede acudir para obtener información. Una organización de servicio para personas con SIDA que se encuentre cerca de su domicilio también puede ser una buena fuente de información, educación y ayuda.

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test  
is manufactured by:

Prueba de detección de anticuerpos OraQuick *ADVANCE*®  
Rapid HIV-1/2 fabricado por:



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